STATUS OF THE MEDICARE TRANSACTION SYSTEM

JOINT HEARING

BEFORE THE

SUBCOMMITTEE ON HUMAN RESOURCES

AND THE

SUBCOMMITTEE ON GOVERNMENT MANAGEMENT, INFORMATION, AND TECHNOLOGY

OF THE

COMMITTEE ON GOVERNMENT REFORM AND OVERSIGHT

HOUSE OF REPRESENTATIVES

ONE HUNDRED FIFTH CONGRESS

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STATUS OF THE MEDICARE TRANSACTION SYSTEM

FRIDAY, MAY 16, 1997

HOUSE OF REPRESENTATIVES, SUBCOMMITTEE ON HUMAN RESOURCES, JOINT WITH THE SUBCOMMITTEE ON GOVERNMENT MANAGEMENT, INFORMATION, AND TECHNOLOGY, COMMITTEE ON GOVERNMENT REFORM AND OVERSIGHT,

Washington, DC.

The subcommittees met, pursuant to notice, at 11:28 a.m., in room 2154, Rayburn House Office Building, Hon. Stephen Horn (chairman of the Subcommittee on Government Management, Information, and Technology) presiding.

Present: Representatives Horn, Sessions, Davis of Virginia, and Maloney, Subcommittee on Government Management, Information, and Technology; Representatives Snowbarger and Kucinich, Subcommittee on Human Resources.

Ex officio present: Representative Waxman.

Staff present: Lawrence J. Halloran, staff director and counsel; Marcia Sayer, professional staff member; R. Jared Carpenter, clerk; J. Russell George, staff director and counsel; Mark Uncapher, counsel; John Hynes, professional staff member; Andrea Miller, clerk; Cherri Branson, minority counsel; and David McMillen and Mark Stephenson, minority professional staff members.

Mr. HORN. Today, we're reviewing the information and data systems in support of America's Medicare program. A quorum being present, we shall begin. Mr. Snowbarger will give the statement of our co-chairman of this hearing, Mr. Shays of Connecticut. He is unavoidably detained, and so I will yield to my colleague for reading the co-chairman's statement as well as any remarks he has on his own.

Mr. SNOWBARGER. Thank you, Mr. Chairman.

Think of Medicare as the trusty family station wagon, the aging, but serviceable, vehicle that we rely upon to carry precious cargo safely and efficiently. Although many cars can go faster and some run more cheaply, we wouldn't think of using anything else.

But our Medicare vehicle needs substantial mechanical repairs if it's going to carry us into the next century without a major breakdown. Under the hood, Medicare's engine, the computerized claims payment system is a sputtering, inefficient tangle of jury-rigged repairs and incompatible parts that no one mechanic can understand and fix.

Rather than continue tinkering with the old system, the Health Care Financing Administration correctly decided to replace the en-

tire Medicare drive train with integrated up-to-date technology. That was almost 5 years ago. Today the repair project, called the Medicare Transaction System, is a costly shambles. After spending more than $40 million dollars, committing to spend more than $100 million, and projecting to spend more than $1 billion, HCFA has halted work on all but the newest and simplest element of the new computer system.

Despite earlier and repeated warnings from the General Accounting Office, congressional committees, including our subcommittees, and HCFA's own technical consultants, the MTS project has been hobbled by poor management, weak risk assessment, and questionable cost assumptions.

Now HCFA is re-evaluating MTS. This is no midcourse correction, but a fundamental reassessment of the MTS process and the prospects for completion before the millennium dawns. Alarms are sounding, and the future of the Medicare program hinges on our response.

At our joint hearing in November 1995, I asked if MTS would succumb to delays and design flaws that doomed other Federal computer acquisitions to early obsolescence or failure. We were assured HCFA was on schedule for transition to MTS beginning in September 1997, with full transition completed by September 1999. We were also assured HCFA welcomed our continuing interest and would periodically report MTS progress and problems. Neither assurance proved very accurate.

Pursuant to our bipartisan request, GAO audited the MTS development process, risk assessment, cost estimates and the year 2000 transition activities. We will hear their findings and recommendations today. They describe critical managerial and technical weaknesses that continue to delay and undermine the MTS effort.

Nor was HCFA forthcoming with information as the process of defining the system requirements churned endlessly and the MTS schedule slipped further. The complexity of the project, the fluidity of the design process, and HCFA's introverted culture combined to veil MTS behind multiple layers of disclaimers and equivocations. For months, while renegotiating the design contract, HCFA would not tell us the exact status of MTS. Now, in view of the 90-day stop-work order issued April 4, HCFA disclaims its own cost estimates because key design elements may be changed.

An unrealistic schedule and an unwillingness or inability to communicate critical information make it very difficult to be confident MTS will ever be the fix Medicare needs to serve beneficiaries and stem losses to fraud and abuse. Today, we ask the HCFA Administrator to assure us once again that MTS is both a realistic vision for Medicare and one within the agency's capacity to realize. We also need to be sure the still distant promise of MTS is not blinding the agency to other near-term cost-effective steps to a unified Medicare claims system.

This joint hearing reflects the determination of all our Members to keep Medicare on a safe course. The Government Management, Information, and Technology Subcommittee, led by my good friend Mr. Horn, is responsible for the oversight of the governmentwide performance and procurement issues. The Human Resources Subcommittee oversees Federal health and human services programs.

Together we will continue to examine the problems and progress of MTS.

Finally, I have to express my disappointment that the Office of Management and Budget declined our invitation to testify today. Their testimony would have been helpful to us. OMB's role in directing agency information, technology and acquisitions is central, and I hope the lessons of MTS will not be lost in the one agency in position to guide all other major system procurements.

To all the other witnesses who accepted our invitation, welcome. Your testimony is an important part of our ongoing MTS oversight, and we appreciate you being here.

Thank you, Mr. Chairman.

Mr. HORN. We thank you for reading co-Chairman Shays' statement. And that is very helpful.

[The prepared statement of Hon. Christopher Shays follows:]

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Statement of Rep. Christopher Shays
May 16, 1997

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But our Medicare vehicle needs substantial mechanical repairs if it's going to carry us into the next century without a major breakdown. Under the hood, Medicare's engine, the computerized claims payment system, is a sputtering, inefficient tangle of gerry-rigged repairs and incompatible parts that no one mechanic understands or can fix.

Rather than continue tinkering with the old system, the Health Care Finance Administration (HCFA) correctly decided to replace the entire Medicare drivetrain with integrated, up-to-date technology.

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Today, the repair project, called the Medicare Transaction System (MTS) is a costly shambles. After spending more than $40 million, committing to spend more than $100 million, and projecting to spend more than $1 billion, HCFA has halted work on all but the newest and simplest element of the new computer system.

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Finally, I have to express my disappointment that the Office of Management and Budget (OMB) declined our invitation to testify today. Their testimony would have been helpful to us. OMB's role in directing agency information technology acquisitions is central, and I hope the lessons of MTS will not be lost on the one agency in position to guide all other major system procurements.

To all the other witnesses who accepted our invitation, welcome. Your testimony is an important part of our ongoing MTS oversight, and we appreciate your being here.

Mr. HORN. Let me briefly read one of my own. As I noted when we started today, we're reviewing the information and data systems that support America's Medicare program. We've been here before on this subject. In November 1995, these two subcommittees held a joint hearing that considered among other matters how existing information technology processes could be incorporated into the Medicare claims system to more effectively identify fraud.

Based on several reports from the General Accounting Office over the years, we've had very serious concerns at that time as well as now about the ambitious Medicare Transaction System or MTS. We believe that the Health Care Financing Administration was ill-equipped to manage such a massive and complex project. We believe that the costs would outweigh the benefits.

Unfortunately, our beliefs have materialized. On April 4th, the Health Care Financing Administration announced that it was exploring other options to develop MTS. The project is in jeopardy. Moreover, we've learned that the Health Care Financing Administration has a serious year 2000 problem as well.

The General Accounting Office has written a report that includes sharp criticism of the Health Care Financing Administration's involvement in the year 2000 software conversion effort of its claims contractors and standard systems maintainers. Needless to say, if the Medicare system is unable to process claims accurately in the year 2000, the impact on Medicare beneficiaries across the country, and, indeed, the entire health care system, could be catastrophic.

Where do we stand now? We need to get assurances today about the future of the Medicare Transaction System as well as the Health Care Financing Administration's management of the year 2000 problem.

[The prepared statement of Hon. Stephen Horn follows:]

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"Status of the Medicare Transaction System"

May 16, 1997

OPENING STATEMENT
REPRESENTATIVE STEPHEN HORN (R-CA)

Chairman, Subcommittee on Government Management,
Information, and Technology

Today we are reviewing the information and data systems that support America's Medicare program. We have been here before. In November 1995, these two subcommittees held a joint hearing that considered, among other matters, how existing information technology processes could be incorporated into the Medicare claims system to more effectively identify fraud.

Based on several reports from the General Accounting Office, we had serious concerns at that time about the ambitious Medicare Transaction System or MTS. We feared that the Health Care Financing Administration (HCFA) was ill-equipped to manage such a massive and complex project. We feared that the costs would outweigh the benefits.

Unfortunately, our fears have materialized. On April 4th, the Health Care Financing Administration announced that it was "exploring other options to develop MTS." The project is in jeopardy. Moreover, we have learned that HCFA has a serious Year 2000 problem as well.

The General Accounting Office has written a report that includes sharp criticism of HCFA's involvement in the year 2000 software conversion effort of its claims contractors and standard systems maintainers. Needless to say, if the Medicare system is unable to process claims accurately in the year 2000, the impact on Medicare beneficiaries across the country, and indeed the entire health care system, could be catastrophic.

Where do we stand now? We need to get assurances today about the future of MTS as well as the HCFA's management of the Year 2000 problem.

Mr. HORN. So I'm delighted to start with panel one. I'm not sure that was a vote on the floor. It is a vote. I'm going to swear you in, then I'm going to go to vote and come back and begin the hearing.

So, gentlemen, you know the routine of the committee. Raise your right hands.

[Witnesses sworn.]

Mr. HORN. The clerk will note that all three witnesses have affirmed.

We are going to be in recess until we've cast the vote and return.

[Brief recess.]

Mr. HORN. The subcommittees will reconvene, and we will begin with the testimony of the first panel. With us is Joel Willemssen, the Director of Information Resources of the General Accounting Office, and if you would identify your colleagues, we would appreciate it.

Mr. WILLEMSSEN. Thank you, Mr. Chairman.

Accompanying me today is Mark Heatwole, Assistant Director, and L.J. Latham, Technical Assistant Director. Thank you for inviting us to testify today on MTS.

Mr. HORN. I might say at this point you know your full statement will be in the record, and so will the GAO study on which it is based, as well as the various exhibits you have. Go ahead.

STATEMENT OF JOEL C. WILLEMSSEN, DIRECTOR, INFORMATION RESOURCES, GENERAL ACCOUNTING OFFICE, ACCOMPANIED BY LEONARD J. LATHAM; AND MARK E. HEATWOLE

Mr. WILLEMSSEN. Thank you, Mr. Chairman. Accordingly, as agreed, I will summarize our statement today. The results are presented in more detail in a report to you that's being released today at the hearing.

In summarizing my statement, my comments will focus on three areas. First, HCFA's management of its interim claims processing environment in which it must operate until MTS software is implemented; second, how HCFA has managed the MTS as an investment and assessed the system's cost and benefits; and third, how effectively sound systems practices have been used in developing the MTS software.

Prior to MTS being fully implemented, HCFA will continue to operate in an interim processing environment for a number of years. In doing this, HCFA plans to reduce the number of existing claims processing systems to one for Part A and one for Part B and cut the number of processing sites by about half, to about 20 nationwide. HCFA was then planning in mid-1998 to move these systems to two planned MTS processing sites and then fully implement the MTS software at these sites sometime after the year 2000.

To successfully handle this major transition, careful and detailed planning is necessary. However, this has not been done. In particular, we see unnecessary risk in HCFA's approach to address the year 2000 computing issue. Failure to adjust systems for the year 2000 could cause payment delays as well as losses due to bypassed system controls. However, HCFA's year 2000 plan has been focused predominantly on its own internal systems rather than its contrac-

tor systems, which are responsible for processing about $200 billion annually in claims.

A further complication is that these contractors may not have much incentive to make changes because HCFA intends to eliminate the contractors once MTS has been implemented. We are concerned that HCFA is relying predominantly on its contractors and has not been closely monitoring their activities or demanding assurances from the contractors that they will indeed fix the systems.

Second, regarding managing MTS as an investment, HCFA cannot make informed technology investment decisions without a valid cost-benefit analysis and an effective assessment of available alternatives. However, this has not been done for MTS. HCFA's estimates of MTS benefits are based primarily on unsupported assumptions. For example, officials said that much of the anticipated program savings would result from automated edits, to identify unnecessary medical services and abuse of billing that could result in excessive payments. They acknowledge, however, that since they have not yet identified the edits to be included in MTS, resulting savings could differ substantially from these estimates.

Another incorrect assumption is that without MTS, costs for claims would continually increase between the years 1993 and 2002. Yet, actual contractor reports for 1994 through 1996, show a drop in costs of about 10 percent. Our chart over here shows the escalation in MTS costs. The figure on the left gives the escalation in total estimated costs for the entire MTS program, while the figure on the right on that chart is the escalation in costs for the software development contract with GTE. As shown on the chart, total estimated costs have dramatically increased almost sevenfold since the 1992 estimate of about $151 million. We now estimate, based on HCFA figures, that the total MTS price tag will be approximately $1 billion.

Regarding the GTE contract, which was awarded slightly more than 3 years ago at about $18 million, actual estimated cost of that contract is now slotted at $92 million. There are alternatives to spending of this magnitude, and we believe that HCFA has a responsibility to explore them. For example, 2 years ago we urged HCFA to investigate commercial off-the-shelf software to help detect billing abuse. We understand that HCFA is currently looking into this.

The third major area of our review is that HCFA is not assuring that sound systems development practice is being followed. HCFA has not developed plans critical to system success, has not managed its schedule well, and has not adequately monitored its contractor's software development strategy.

If I may point you to the other chart we have here, the chart has six figures. Each of those figures represents a major release or major module or piece of the software that GTE is responsible for developing. But what we've seen on the requirements for each of those releases is continued volatility. Even 3 years after the contract has been awarded, there is still not agreement on exactly what the system is supposed to do. This makes it, of course, very difficult for GTE to go ahead and program, and this is a key critical continuing concern.

Deficiencies in critical systems development processes provide warnings of weaknesses in the management capability of HCFA and its contractors. These factors all increase risk. Among the critical areas that remain unresolved include missing or inadequate plans for requirements management, configuration management, and systems integration.

In summary, we believe serious weaknesses with MTS exist. These weaknesses call into question whether MTS, without significant change, will be able to perform as required.

Further, given the escalation in estimated costs, we have concerns whether MTS is worth the estimated $1 billion price tag. More can and must be done if HCFA is to obtain the type of system that it needs.

Our report that's being released today includes 20 major recommendations to help HCFA enhance the likelihood of acquiring a cost-effective system. We are encouraged that in commenting on a draft of our report, both OMB and HHS agreed with our findings and have agreed with all of our recommendations. However, our recommendations must be effectively implemented in order for a project such as MTS to succeed.

That concludes the summary of my statement. I would be pleased to address any questions you may have.

Mr. HORN. Well I thank you very much for that statement.

[The prepared statement of Mr. Willemssen follows:]

Messrs. Chairmen and Members of the Subcommittees:

We are pleased to join you today in examining the status and prognosis for success of the Health Care Financing Administration's (HCFA) Medicare Transaction System (MTS), being designed to bring Medicare claims processing into the next century. Developing this system is not an easy task. Attempting to replace nine separate automated information systems with a single, unified system, is clearly a very complex endeavor.

The goals of MTS include improved customer service; reduced operating expenses; more effective control over claims processing; better oversight of contractors; substantial administrative savings; better protection of program funds against waste, fraud, and abuse; and the ability to accommodate managed care and other alternative payment methodologies. One specific, basic improvement that MTS is expected to provide over the current environment is the need to modify only one system when changes, such as those following enactment of legislation, affect Medicare payments. At present, each system must be individually changed--an expensive, time-consuming process.

Both we and the Congress have had long-standing concerns about the development of MTS.[1] Today we are issuing a report that discusses our analysis of HCFA's progress in

[1]A list of reports and testimony related to MTS appears at the end of this statement.

managing the development of this system.[2] Eighteen months ago we similarly testified on early symptoms of unnecessary risk to this project, and in 1994 we reported on its benefits and acquisition risks.[3] The fact remains that despite much hard work and some progress, critical weaknesses--both managerial and technical--continue to exist. These weaknesses call into serious question whether MTS, without significant change, will be able to perform as required. Further, as we will illustrate, costs have been escalating sharply; even if performance is as expected, we would have to ask: Is it worth the estimated $1-billion-dollar price? Could similar system functions be acquired at significantly lower cost? We believe that more can and must be done if HCFA is to obtain the type of system it needs. Our report includes 20 major recommendations to help HCFA enhance the likelihood of acquiring the kind of system it must have, in a cost-effective manner.

My statement today will discuss the actions HCFA has taken to date, and where these steps leave the agency in its development of a system that can handle Medicare claims processing into the next century. I will then cover the three related major areas that we believe need the most attention. The first area involves HCFA's *management of the interim*

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[2]Medicare Transaction System: Success Depends Upon Correcting Critical Managerial and Technical Weaknesses (GAO/AIMD-97-78, May 16, 1997).

[3]Medicare Transaction System: Strengthened Management and Sound Development Approach Critical to Success (GAO/T-AIMD-96-12, Nov. 16, 1995) and Medicare: New Claims Processing System Benefits and Acquisition Risks (GAO/HEHS/AIMD-94-79, Jan. 25, 1994).

claims-processing environment in which it must operate until conversion to MTS or another system has been completed; this includes addressing adaptations required by the century change that is only 959 days away.[4] The second area of concern relates to *managing the development of MTS as an investment*. This means using cost/benefit analyses and other tools to continually track and assess whether funds spent on MTS will contribute to a return on this investment, as measured not only monetarily but against the system's own goals as well. Finally, *sound systems-development practices* are critical in order to reduce risk and help ensure quality, timeliness, and cost containment. We continue to see major gaps in HCFA's application of sound systems-development practices--practices that are essential to assisting management in controlling the development of systems requirements and software.

THE MEDICARE TRANSACTION SYSTEM

Medicare is an enormous program, and it will only get bigger. As the nation's largest health insurer, it serves some 38 million Americans by providing health insurance to

[4]In brief, this entails expanding the date field or rewriting program code to differentiate between 1900 and 2000; many systems today use only two digits for the year, such that "00" could be read as either 1900 or 2000. For an explanation of the expected impact of the year-2000 change on computer systems, see Year 2000 Computing Crisis: Strong Leadership Today Needed To Prevent Future Disruption of Government Services (GAO/T-AIMD-97-51, Feb. 24, 1997).

those aged 65 and over, and to many of the nation's disabled. It now disburses over $200 billion in health care benefits every year. With an aging population and a rapidly expanding workload, this figure is expected to reach $288 billion by 2000, at which time the Medicare program expects to be processing one billion claims annually.

The Medicare program is divided into to areas--part A and part B. Part A encompasses in-patient services, with claims paid to hospitals, skilled nursing facilities, hospices, home health agencies, and rehabilitation centers. Part B comprises outpatient services, with claims paid to physicians, laboratories, equipment suppliers, and other outpatient providers and practitioners.

Claims processing for the Medicare program is handled at some 45 sites throughout the country by about 70 private companies under contract with HCFA. Contractors handling part A services, called intermediaries,[5] have been using three different computer systems to process claims; those handling part B, called carriers, use six different systems.[6]

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[5]Intermediaries also process some part B claims.

[6]One of the three part A systems was recently converted, leaving a total of eight--two part A systems and six part B.

In order to handle the anticipated increases in volume and improve the efficiency and effectiveness of Medicare operations, HCFA is developing one unified computer system to replace today's operating environment. In January 1994 HCFA awarded a contract to a software developer to design, develop, and implement a new, government-owned, automated claims-processing information system, to be called the Medicare Transaction System, or MTS.

HCFA ACTIONS TO DATE

As part of my presentation today, I would like to discuss three charts that should help illustrate our major points. Copies of these charts appear at the end of my statement. In an attempt to achieve some savings before MTS is fully operational, HCFA is now undertaking several actions to prepare for the interim operating environment, while simultaneously continuing its development of the final system.

As our first chart indicates, one interim step involved selecting one system from the initial nine systems to process claims for Medicare part A, and another for part B. The part A and part B systems have been selected and conversion has begun. A second, planned step entailed cutting the number of processing sites by over half, to about 20 nationwide. HCFA then planned to move data processing from these 20 consolidated

sites to two planned MTS processing sites in mid-1998. During this interim period HCFA is also relying on its contractors to revise their systems to accommodate year-2000 processing. Throughout this process HCFA's software development contractor was to be conducting activities to develop the MTS software.

These software development plans are now, however, on hold for 90 days. On April 4, 1997, HCFA announced that, following a recent management review, it was redirecting its software development contractor to focus solely on the managed care module of MTS--the first of six planned releases. While reaffirming its faith in MTS as the best information technology to take Medicare into the next century, HCFA officials said they will use this time to examine alternative methods for achieving their MTS goals.

INTERIM ENVIRONMENT AND YEAR 2000 PRESENT SERIOUS CHALLENGES

The first main problem area involves HCFA's interim operating environment--before MTS--and the challenges of the coming change of century. HCFA has approached managing the environment in which it will operate for the next 3 years without adequate planning. To successfully handle the claims workload, consolidate existing processing sites, address year 2000-related issues, and convert from the original nine systems to two, careful and detailed planning is necessary. This has not been done. While HCFA

is already beginning to convert its systems and consolidate its sites, few plans exist to guide these activities. What sorts of plans are needed? At minimum, a schedule and estimate of resources required for transition to the interim environment, details defining contractor responsibilities, and an approach for tackling the potentially complex year-2000 issue.

To simultaneously convert systems for the interim environment while at the same time managing ongoing development of MTS is risky enough; this risk is further magnified by HCFA's lack of experience in undertaking such a complex project. In such an environment, we believe it is especially important that HCFA develop specific performance measures against which the interim systems can be assessed. Performance measures could show that the "interim" systems may be all that is needed, or could be used to help management make refinements to its modernization effort as it unfolds.

We also see unnecessary risk in HCFA's reliance on its Medicare contractors to address the year-2000 issue. Information systems worldwide--including those that process Medicare claims--could malfunction or produce incorrect data simply because they have not been designed to handle dates beyond 1999. Failure to adjust systems for 2000 and beyond could cause payment delays, as well as losses due to bypassed system controls that flag claims that should be paid by a beneficiary's other insurer. Since "00" could be read as 1900 instead of 2000, all date-dependent calculations would be affected; this

would have an obvious impact on the computed age of a beneficiary and, therefore, on his or her eligibility. For example, an individual born in 1920 might have been receiving benefits since turning 65 in 1985. Such benefits could, however, cease in 2000 if the computer system, reading 2000 as 1900, saw the individual as *negative* 20 years old--not even born yet.

The timing of HCFA's transition strategy makes the claims-processing contractors' task--assessing, planning, and implementing whatever changes are necessary--even more of a challenge. For example, the contractor for the single system selected to process part B claims will have to handle the conversion of the five other, existing part B systems--while modifying the chosen system to be year-2000 compliant. Yet HCFA officials have not closely monitored these critical activities, or demanded certification from contractors that their systems will be made year 2000-compliant. A further complication is that these contractors may not have much incentive to make these adaptations properly, because HCFA intends to eliminate them once MTS has been fully implemented. Officials are "surveying" contractors on the year-2000 issue, however, and have requested estimates of when the systems will be made compliant.

To help HCFA effectively manage its interim Medicare processing environment, our report recommends that the Secretary of HHS direct that the HCFA Administrator

- prepare plans that detail the steps involved in making the transition to the single part A and part B systems, define how systems will be converted to address potential year-2000 problems, and delineate the steps necessary for thorough systems testing before conversion;
- establish a means of assessing performance in the critical early stages of the transition, and apply any lessons learned to planning for MTS; and
- help ensure reliable operation of systems through the year 2000 by identifying management and oversight responsibilities, assessing the timing and likely severity of impact if adaptations are not adequate, developing contingency plans, and reporting progress regularly to HHS.

MTS IS NOT BEING MANAGED AS AN INVESTMENT

Our second major area of concern involves investment management. One cannot make informed technology investment decisions without a valid cost/benefit analysis, knowledge of available alternatives, and an evaluation of how proposed technology benefits will contribute to improved mission performance. Carrying out these assessments is more than simply a best practice; it is required by law. As you know, last year's Clinger-Cohen Act seeks to maximize the return on investments in information systems by instituting sound capital investment decision-making.

Under Clinger-Cohen, agencies must design and implement a process for maximizing the value and assessing and managing the risks of information technology acquisitions. Further, this process is to be integrated with the processes for making budgetary, financial, and program management decisions, and include criteria to be applied in considering whether to undertake a particular information systems investment.

Specifically, the process should provide for (1) identifying information systems investments that would result in shared benefits or reduced costs for other government agencies, (2) identifying quantifiable measurements of benefits and risks of proposed investments, and (3) the means for senior management to obtain information on the progress of information systems investments. None of this has yet been done effectively for MTS.

HCFA's estimates of MTS benefits are based primarily on unsupported assumptions. For example, officials said that much of the anticipated programmatic savings would result from automated edits to identify unnecessary medical services and abusive billing that could result in excessive payments. They acknowledge, however, that since they have not yet identified the edits to be included in MTS, resulting savings could differ substantially from the estimates. Another incorrect assumption is that without MTS, costs per claim would continually increase between 1993 and 2002. Yet actual contractor cost reports for 1994 through 1996 show a drop of about 10 percent.

Our second chart illustrates the escalation of MTS costs; the figure on the left is an estimate, using HCFA data, of total program costs through complete implementation, while the one on the right is software-development contract costs only. I want to make clear that the dates on these figures refer to when the estimates were made.

Both figures do show recent steep increases. In total, estimated MTS costs have jumped 7-fold in 5 years, from $151 million in 1992 to about $1 billion today. I should point out that the $1 billion figure includes costs for the transition to the interim environment and to acquire MTS operating sites. Many aspects of the overall development effort remain vague; for example, requirements still have not been defined. Absent this, estimates of total software-development costs are, of necessity, extremely rough at best.

There are alternatives to spending of this magnitude, and we believe--especially given the recent escalation of costs--that HCFA has a responsibility to explore them. Two years ago we urged HCFA to investigate commercial, off-the-shelf software to help detect billing anomalies; we understand that this research is continuing. We believe that, combined with administrative savings accruing from the consolidation of systems, commercial software could allow HCFA to realize substantial savings now. According to HCFA's estimate, MTS will not be fully operational, at the earliest, for at least 3 years. During that period, hundreds of billions of dollars will have been spent on Medicare claims.

As part of the complete MTS system, HCFA plans to establish two MTS claims-processing sites and a data operations and analysis center. This decision was made with inadequate analysis in terms of decision criteria, alternatives analysis, and technical risk analysis. The decision to have two processing sites was made on the basis of data-storage and disaster-recovery considerations only. Given the importance of these steps, our report recommends that the Secretary of HHS withhold funding for the MTS operating site contracts until an approach has been selected that is based on these crucial analyses.

Managing a project as an investment also requires strong managerial oversight; this has not been the case with MTS. Consistent senior-level involvement in major decisions is still lacking. Many of the critical MTS investment decisions have been made without the involvement of HCFA's executive decision-making body, the MTS management board. HCFA is, however, making positive changes; it has designated a chief information officer and has established an investment review board.

To help HCFA minimize unnecessary spending while developing and implementing MTS, our report recommends that the Secretary of HHS direct that the HCFA Administrator justify continuation of MTS with valid cost/benefit and alternatives analyses that include goals for reaching programmatic savings and that link estimated

savings to specific Medicare claims-processing improvements--and take appropriate action on the basis of these analyses.

Our report also recommends that the Secretary of HHS assist HCFA by providing oversight in accordance with legislative provisions in the Clinger-Cohen, Paperwork Reduction, and Federal Acquisition and Streamlining Acts. This should include monitoring by HHS' chief information officer. The report further recommends that, in accordance with Clinger-Cohen, the Office of Management and Budget utilize its enforcement authority to ensure HCFA's compliance with the act, including the cost-justification provision.

NOT FOLLOWING SOUND SYSTEMS-DEVELOPMENT PRACTICES THREATENS QUALITY, TIMELINESS, AND COST CONTAINMENT

The third major problem we see is that HCFA is not ensuring that sound systems-development practices are followed. Because of this, the agency has decreased the chances of controlling the development of systems requirements and software. HCFA has not developed plans critical to systems success, has not managed its schedule well, and has not adequately monitored its contractor's software-development strategy. Further, because of faulty assumptions on the part of the contractor, estimates of

software-development costs are not reliable. Consequently, the risk that such estimates could rise before the project is completed is very real. Finally, HCFA has not implemented a concerted program to minimize risk.

Attention to these steps is common to organizations that succeed in acquiring well-performing automated information systems. Not managing in this way significantly increases the threat to overall system quality, timely completion, and reasonable cost expenditures.

Our final chart today shows what can happen when such guidelines are not followed. This illustrates how the number of systems requirements changed over time for the first five contract releases of MTS. The lack of symmetry illustrates the enormous volatility in how many and what types of systems requirements are seen as necessary as development progresses--and this after several years of attempting to define what the system will actually do.

Deficiencies in several critical systems-development processes provide early warning of weaknesses in the management capability of HCFA itself and of its contractors. These factors all increase risk. Critical risks that remain unmitigated include (1) missing or inadequate plans for three important components of systems development--requirements management, configuration management, and systems integration; (2) the compression of

MTS' development schedule; and (3) the lack of valuable metrics, which are measures of software quality and performance. Taken together, the number and significance of these unmitigated risks, along with several others, raises the question of whether MTS can become the management tool that HCFA expects.

An aspect of the MTS schedule that we see as troubling is that individual systems-development phases now overlap to a dangerous degree. Systems are typically constructed in five phases: *analysis, design, development, testing and validation,* and *implementation.* When, for example, testing and validation begins before development has been completed, or implementation begins before the end of testing, the resulting overlap can clearly cause problems. These steps were meant to be predominantly sequential because each phase's success depends, in part, upon adequate progress in the previous phase. If a contractor advances too far into a succeeding systems-development phase before sufficient progress has been made in the previous phases, the risk of technical problems increases significantly. The current HCFA schedule for MTS shows concurrency in all five phases between September 1997 and September 1998, and overlap is also present in the schedules for each planned release, such as managed care.

To help ensure the success of MTS, our report recommends that the Secretary of HHS require that the HCFA Administrator, before proceeding further with MTS development, direct and remain accountable for

- completing and implementing plans that are critical to effective systems development;
- requiring an independent evaluation of the MTS contractor's software-development capability prior to beginning that phase;
- completing a new and integrated MTS program schedule for the entire initiative, including the interim, and resources and costs for each task; it should also minimize overlap in the systems-development phases; and
- mitigating critical risks by designating an official accountable for risk management, and ensuring that this individual implements a process that will, among other elements, identify and quantify significant risks, establish time frames for assessing status and for mitigation, and develop measures for assessing mitigation effectiveness.

Finally, we believe that closer oversight by both HHS and OMB is necessary to ensure that MTS or any alternative system is developed along the lines that we are recommending. In particular, we see HHS as a critical player in assisting HCFA and in monitoring its actions. For its part, OMB is authorized under Clinger-Cohen[7] to take enforcement actions to ensure that HCFA complies with the law's provisions, including the mandate to justify major information technology projects with sound, investment-based analyses.

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[7]Section 5113 (b)(5).

In summary, HCFA is proceeding with a project that has serious managerial and technical weaknesses. In order to bring Medicare claims processing into the next century with confidence, we believe that HCFA must manage as an investment any information technology it seeks to acquire. This means performing the analyses necessary to predict the kind of return the investment is likely to provide, short-term and long-term--in a fiscal as well as technical sense. HCFA then has an obligation to manage such a challenge through the use of sound systems-development practices.

We are encouraged that, in commenting on a draft of the report being released today, both HHS and OMB have recognized the problems we have identified and agreed with all of our recommendations for addressing them. However, these recommendations must be effectively implemented in order for a project such as MTS to be successful.

This concludes my statement. I would be happy to respond to any questions you or other Members of the Subcommittees may have at this time.

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ATTACHMENT ATTACHMENT

RELATED GAO PRODUCTS

Medicare Transaction System: Success Depends Upon Correcting Critical Managerial and Technical Weaknesses (GAO/AIMD-97-78, May 16, 1997)

Year 2000 Computing Crisis: Strong Leadership Today Needed To Prevent Future Disruption of Government Services (GAO/T-AIMD-97-51, Feb. 24, 1997)

Medicare: Millions Can be Saved by Screening Claims for Overused Services (GAO/HEHS-96-49, Jan. 30, 1996)

Medicare Transaction System: Strengthened Management and Sound Development Approach Critical to Success (GAO/T-AIMD-96-12, Nov. 16, 1995)

Medicare: Antifraud Technology Offers Significant Opportunity To Reduce Health Care Fraud (GAO/AIMD-95-77, Aug. 11, 1995)

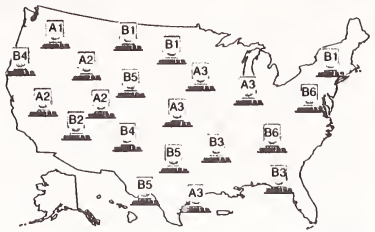
Medicare Claims: Commercial Technology Could Save Billions Lost to Billing Abuse (GAO/AIMD-95-135, May 5, 1995)

Medicare: New Claims Processing System Benefits and Acquisition Risks (GAO/HEHS/AIMD-94-79, Jan. 25, 1994)

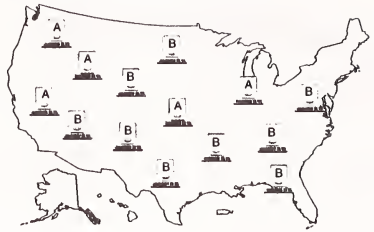
(511220)

GAO HCFA Strategy for Transition to MTS

From:
9 separate claims-processing systems at about 45 sites

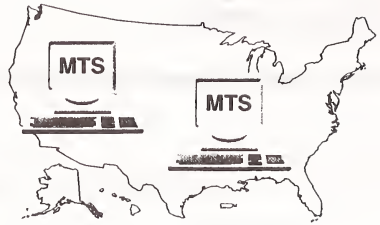


To:
A single part A and a single part B claims-processing system at about 20 sites



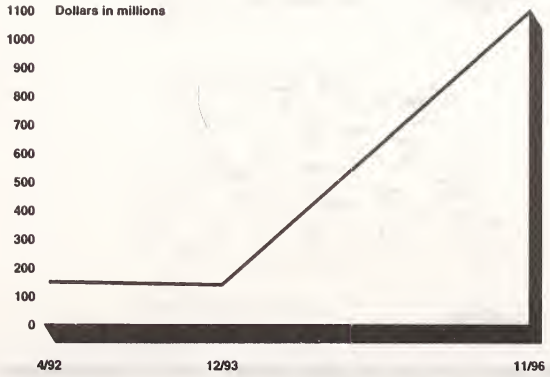
From:
A single part A and a single part B claims-processing system at about 20 sites

To:
The Medicare Transaction System at 2 sites

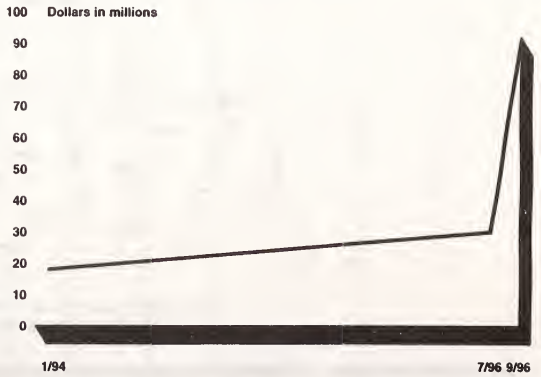


GAO Medicare Transaction System: Escalating Costs

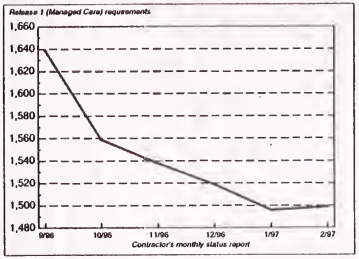
Total Estimated Costs

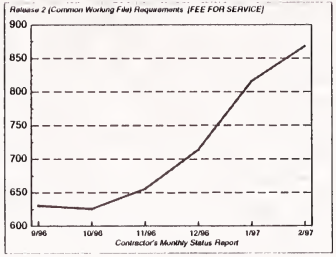


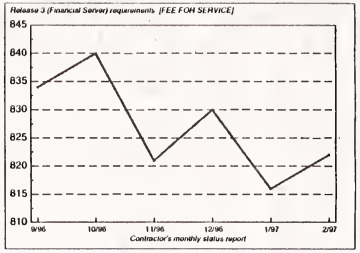
Software Development Contract Costs

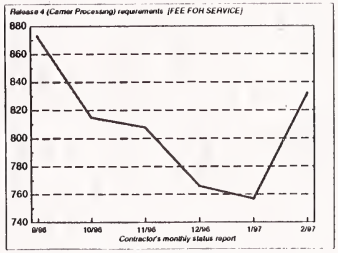


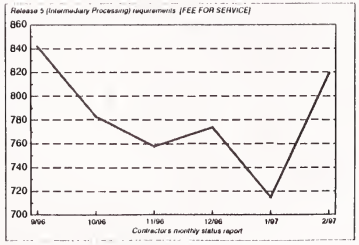
GAO Volatility of MTS Requirements

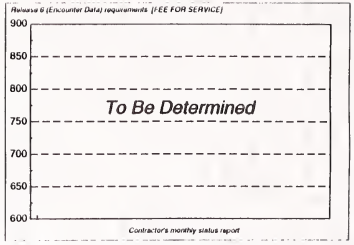












NOTE: Scale above [600-900] for purposes of illustration only, numbers of requirements for this release are not yet available

Mr. HORN. I'm going to only ask one or two questions and yield to my colleagues. But the first question I want to ask: you've been with GAO since 1979. Did you have anything to do with reviewing what the FAA did in terms of their failures in computerization and what IRS has done in its failures on computerization? Were you involved in those reviews at all?

Mr. WILLEMSSEN. I participated and led numerous reviews at the Federal Aviation Administration, not at the IRS.

Mr. HORN. Not at the IRS, because my question is—and I think you probably have some knowledge of the IRS since they did take a look at it—what's different about this? Are they going down the same path that led to $4 billion down the drain with FAA, $4 billion down the drain with IRS? Are we headed there?

Mr. WILLEMSSEN. I would say we are concerned that we do see certain similarities, but I am encouraged by recent actions at OMB, HHS, and HCFA, that they intend to stop and reassess and not proceed in a hurried manner, but at the same time expeditiously try to do what's right. We would encourage them to base future decisions on full and complete analysis rather than deciding and then putting together analysis to support those presupposed decisions.

So I have seen some similarities, but again, we're encouraged by recent actions. We support the stop-work order of April. We think that was a recognition that there are problems, and that we have to halt and reassess and do what's best from here on out.

Mr. HORN. Is part of the problem the failure to have initial planning cost-benefit analysis, all of which you mentioned, and the GAO report released today mentions, or is it the management of the project as it evolves where decisions are made, not simply drift, and everybody's ideas get put into the mix? And that, I think, was some of the problem in the other two agencies.

Mr. WILLEMSSEN. Yes, I think it's—it definitely has elements of both. We think, for example, in accordance with Clinger-Cohen, it is especially critical for a project such as this, the agency should be routinely providing the estimated cost of the project. Unfortunately, that kind of information has not been available until very recently so that key stakeholders, such as critical congressional committees such as yours, can keep an eye and watch on what's going on. That has not been done. And we would hope that from this point forward that kind of continuing investment analysis, tracking what the estimated costs and benefits and risks are going to be, and comparing them to what the actual—what actually occurs, is going to happen.

In this particular case, a key element that I want to emphasize again is the fact that requirements for what you want the system to do have to be defined before you're going to be able to really do—write software and develop a product. More than 3 years after the contract is awarded, we still aren't at that point.

Mr. HORN. Let me ask you about an issue that is of great interest to this subcommittee which began focusing on this over a year ago. In your report and in your testimony, you're highly critical of the Health Care Financing Administration's management of the year 2000 conversion efforts and of the existing claims processing contractors as well as the standard systems maintainers. Now the Health Care Financing Administration responded that it has relied

on its contractors to make necessary software changes in the past and expects they will be able to make these changes in the future.

The obvious question is: What are the risks for the Medicare claims processing system if these year 2000 software changes are not successfully completed, and what do you think of the plan they have to move ahead in that area? In the recent report of the Director of the Office of Management and Budget, as the basis for their budget estimate, which is absolutely off the wall in terms of the $2.3 billion cost to the Federal Government, they had these agencies turn in a semi-timetable. I can't say it was a plan, but it was a timetable. And one of the problems is it seems to all pile up in the year 1999, and not much time is left with some agencies to really work the bugs out of it. And I just wondered what your reaction is on this?

Mr. WILLEMSSEN. We've been very concerned with HCFA's plans to address the year 2000 issue with its contractors. Until very recently its plan essentially dealt with only its internal systems, and it was relying entirely on its contractors to make the fixes. We thought that was a highly risky approach. There weren't contingency plans developed, and still aren't. In the event there is a failure, what are we going to do; what's the backup plan? There has been no assessment of the severity of the impact, in the event there is year 2000 failure, what would actually happen to claims. That's another area that we think definitely needs to be addressed.

Mr. HORN. On that point, what would happen to claims? Obviously, one is eligibility——

Mr. WILLEMSSEN. Potentially.

Mr. HORN [continuing]. Just are you 65?

Mr. WILLEMSSEN. Definitely.

Mr. HORN. And are you subtracting from 1900 or the year 2000, 00. And I assume there are other things, such as hospital days, nursing home days, all the rest of the scheduling.

Mr. WILLEMSSEN. Dating is especially critical, but that assessment of the particulars, we have not seen that yet, so we are obviously concerned. We are also concerned because HCFA hasn't required contractors to provide them assurance that they're going to fix it. We would assume that that would be a bare minimum step.

Mr. HORN. In other words, in neither the hardware nor the software they're examining to see that they're 2000-compliant—or not examining?

Mr. WILLEMSSEN. One of the contractors we visited was examining the software. One of the difficulties, though, is that software is sent to multiple locations. What assurance does HCFA have that each location is using the same version of the operating system, same data base management system, same telecommunications, same communications, and other peripherals? They're relying on the contractor. So we definitely have concerns in that area.

Mr. HORN. Is there a separate chief information officer for the Health Care Financing Administration?

Mr. WILLEMSSEN. It's one positive note in our report that HCFA has recently established the position, and will be filling it shortly as part of their reorganization, which I believe is going into effect this summer.

Mr. HORN. In other words, they've had a year to do something about this since the law was passed, maybe a year and a half, and they haven't filled the position yet?

Mr. WILLEMSSEN. Well, actually, under the law, HHS is required to have the chief information officer. And many of the component agencies often follow suit, but are not legally required to do so.

Mr. HORN. I now yield 10 minutes to the gentleman from Kansas, Mr. Snowbarger.

Mr. SNOWBARGER. Thank you, Mr. Chairman.

I've got a couple of questions specific to MTS, but let me ask an overall question first. One of the problems it seems that we're dealing with here is that the original estimates were far understated, so much so that it would seem like anybody that knew what they were doing would have come a little bit closer anyway. My question to you is: To what extent is GAO involved either formally or informally in the original RFP process and trying to make those estimates, determinations of cost to the program?

Mr. WILLEMSSEN. We are only involved from an evaluation perspective, from an external perspective. We are not involved in actually getting in with the agency and helping them make those decisions. We do participate as an—in an evaluative role.

Mr. SNOWBARGER. So basically you come in after the fact and say, here's your estimate, but here are the mistakes you've made in trying to come up with that or——

Mr. WILLEMSSEN. Well as Chairman Horn pointed out, in this case, though, we have previously reported on many of our concerns with the Medicare Transaction System. I guess I'm trying to make the point that we can't tell HCFA, obviously, what to do. We can offer suggestions, offer recommendations as it pertains to cost estimates. And, in fact, that's what we tried to do in the report we're releasing today. But we can't direct action.

Mr. SNOWBARGER. I understand that. And I guess my concern is—and the chairman mentioned two or three different underestimations, particularly in terms of computerization technology—that it seems like we're not doing a very good job with coming up with estimates in the first place. When it comes in with a significantly understated cost, Congress is more likely to accept the program and accept the direction; whereas if we knew the real cost, perhaps we'd have a different assessment of cost benefit analysis program. And I'm just trying to figure out a way that we can get a better, more accurate job in getting those estimates in the first place.

Mr. WILLEMSSEN. I think, if I may——

Mr. SNOWBARGER. Sure.

Mr. WILLEMSSEN [continuing]. Insert, Congressman, I think full implementation of the Clinger-Cohen Act, which was enacted in the last year, would go a long ways in doing that which is going to force agencies to take an investment approach to their information technology acquisitions and at all times, from cradle to grave, have an understanding of what the costs, benefits, and risks are on a schedule and an actual basis.

Mr. SNOWBARGER. What's the—if you could single out any change that you recommend to HCFA, what would that change be for the success of the MTS project?

Mr. WILLEMSSEN. I would say the one thing that we are greatly encouraged by is the stop-work order and the recognition——

Mr. SNOWBARGER. I'm encouraged by that, too, because they are—they've been failing thus far. I'm glad they're stopping. But just because they stopped doesn't mean they're going to proceed in the right direction once they gear up again.

Mr. WILLEMSSEN. And the most important next step is to do the analyses that we pointed out both in the statement and in our report that drive the decisions rather than vice versa, that HCFA or whoever makes a decision and then puts together an analysis to support that decision. We think, for example, in the investment area, cost benefits and risks, there needs to be a full assessment of available alternatives on costs, benefits, and risks of each of those alternatives for what can best meet the needs of the Medicare claims processing area. That is especially critical.

Mr. SNOWBARGER. Do you have any assurance or confidence that that kind of assessment is going to be done?

Mr. WILLEMSSEN. I have more confidence today than I would have stated 6 weeks ago.

Mr. SNOWBARGER. I'm not sure how comforting that is, but that's OK.

What recommendations have you made that have not been heeded, but you think would make significant impact on MTS project?

Mr. WILLEMSSEN. Unfortunately the same ones that we just talked about. When we testified 18 months ago, we were pushing hard to have a full disclosure of investment cost benefits and risks. And subsequent to that, that did not occur. We are certainly hoping at this point that it will.

Mr. SNOWBARGER. The combination of your two answers is not very comforting at all, because basically you're saying you're hoping you're going to get what you asked for 18 months ago but didn't get then, but you've been assured you will get it in the future.

Mr. WILLEMSSEN. Well, the one distinction is there has been the stop-work order and a general recognition. When these kind of figures are disclosed, I don't think the project can go much further without some substantial change.

Mr. SNOWBARGER. I thank you.

Thank you, Mr. Chairman.

Mr. HORN. I'm now delighted to recognize the gentleman from Ohio, Mr. Kucinich.

Mr. KUCINICH. Thank you very much, Mr. Chairman, members of the committee.

Mr. Chairman, I certainly appreciate the work which this committee is doing in trying to protect the taxpayers' investment in computer systems which are designed to handle not just bits of information, but the—the complex social and medical concerns which the American people have. We can sometimes get so bogged down in the technical details of computer or program failure that we forget that millions of Americans depend on these programs to work, and if there's a glitch in a computer which has an effect on someone's delivery for benefits or their being able to even be listed at all, that's something that concerned the Congress. So it's appropriate we're here.

I would just like to add to this discussion, Mr. Chairman a slightly new wrinkle, which perhaps the GAO has heard about, and the Chair, I'm sure, is familiar with. Since 1984, the Federal Government has spent over $2 billion in Federal funds to help develop statewide computer tracking systems to catch deadbeat dads and to make them pay child support. Only eight—and I'm sure the GAO knows all about this. Only eight States currently have systems that are certified by the Department of Health and Human Services. And furthermore, since the inception of Ohio's State Enforcement Tracking System, Ohio has spent, since 1988—now follow this, Mr. Chairman—$35 million of Federal money on the development and installation of the system. Yet only one county in all of Ohio, all of 88 counties, is currently on-line. That's Pickaway County, which has 140 delinquent child support cases. Are you following this, Congressman Snowbarger; 140 delinquent child support cases, and yet we've spent $35 million already. Now you want to talk about "deadbeat dads." How about a "deadbeat" computer system? Right now they're talking the current projected costs of Ohio's computer system is about $92 million. I don't know what success we're having in tracking those 140 cases in Pickaway either.

We have a mess here of a major order, and while this is tangential, this issue is tangential to what we're speaking about today, let it be said that this problem of computer chaos is systemic. It is not related just to MTS. Certainly, the Senate Governmental Affairs Committee in their report in October 1994, in talking about the billions that have been wasted in the computer systems, have hit a nerve, but I want the GAO to know, and, Mr. Chairman, this would be, I believe, a worthy topic for a future meeting of this committee, where perhaps the GAO could grace the committee meeting with their attendance as well. I've sent a letter to Chairman Christopher Shays about it outlining some of my concerns.

But you know, we've—I think all of us share the concern that the Federal dollars be used to deliver services. We're putting the money into hardware, and we're not creating any solutions. We're creating more problems and more waste.

So thank you, Mr. Chairman.

Mr. HORN. On that tale of horrors that you've described, we could endow the helpless spouse and children left behind at about $657,000 endowment, and that would draw, if properly invested, $60,000 a year to solve some of the problems at home.

Mr. KUCINICH. Exactly, Mr. Chairman. And when you think about how you could distribute those benefits in a different way, it boggles the mind. And that's why this committee's work is so important to the American people, and I appreciate the Chair's further insights on this.

Mr. HORN. Well, I thank the gentleman from Ohio. One of my pet targets last year was the Columbus Processing Center of the Department of Defense. Now they've assured me that they've straightened that out, and maybe you and I and whoever else we could get to go along should have a field hearing out there and look at both of them.

Mr. KUCINICH. Did the Chair say a field hearing or a field day?

Mr. HORN. A little of both.

Mr. KUCINICH. Thank you.

Mr. HORN. Would the General Accounting Office like to comment on that?

Mr. WILLEMSSEN. Yes. Congressman, I wanted to let you know that we will be issuing a report on June 30, to Congressman Hyde and Congressman Woolsey on child support enforcement systems. I would expect that report to be released probably sometime in the July timeframe. We would be more than pleased to come up and brief you on it.

Mr. KUCINICH. Thank you, Mr. Chairman. Thank you.

Mr. HORN. I hope you're including in that the Horn-Maloney Debt Improvement Act which Commissioner Adams in Massachusetts said made his day, and he plans to collect millions from "deadbeat dads" using the access to the Federal systems to track addresses and everything else. But I was rather pleased when he called me up that day and said that law pleased him, as opposed to some others we passed down here.

Now I'm delighted to yield to the gentleman from Virginia, who is an expert in this area. Mr. Davis.

Mr. DAVIS OF VIRGINIA. Thank you. I don't know. I used to be an expert.

You know the IT field is changing so rapidly and needs change, but I was puzzled. Two years ago, the IV&V contractor gave warnings to HCFA. I don't know how they responded to it. But I would like to know GAO's best observation of HCFA's management structure. How does this fit into the reorganization currently going? And then GAO's responses to the IV&V contractors' warnings on this, and was it satisfactory?

These systems can be so complex. I know how difficult it can be sometimes, how sometimes these projects are poorly defined at the beginning, and there are different understandings between the contractor and the Government. And that's why we have IV&V contractors to help oversee that and give warnings and the like, because it's very often beyond the abilities and the capabilities of in-house to understand everything that's going on. I am just interested in how that process got astray here——

Mr. WILLEMSSEN. I totally agree with your comments on the need for help and oversight from an IV&V. Frankly, HCFA isn't in the business of going out and acquiring major software projects, so it's unrealistic to think they would go out the first time and acquire this huge system and do it incredibly well. They don't have the experience to do it. That's why we were supportive of them getting an IV&V contractor, Intermetrics. Ideally, it would have been obtained before the contract was awarded, to give them additional support. But agencies such as HCFA, throughout the Federal Government, as you noted, need support. They don't always have the expertise to carry it out themselves.

One area of disappointment that we've noted is that, not in all cases, some of the IV&Vs' findings were not heeded by HCFA. The IV&V pointed out many of the same risks in the software development area that we're illustrating in our report today. HCFA was aware of those and didn't take the necessary actions at the time.

Mr. DAVIS OF VIRGINIA. I'm not sure why they wouldn't. I mean, this is something that most contracting officers and procurement

professionals when they get these, they understand, it's a complex nature, would not want to go out on their note. They want to have the background support. They know they have to stand up and answer to this someday before a committee like us. And I don't understand why they weren't heeded, and he'll get to that, I guess, a little later. Any thoughts as to why it wasn't heeded?

Mr. WILLEMSSEN. I think, again, going back to the major underlying cause for this, there was a severe underestimation of the complexity involved, something you touched on in your earlier comments. And I think, given that, when somebody from the outside identifies problems, there is sometimes a general feeling, well, that doesn't really seem that significant, I don't think we'll have to deal with that. Let's just go ahead and progress forward.

Mr. DAVIS OF VIRGINIA. Was this a cost-driven procurement, or was this a value-driven procurement in terms of awarding the original contract?

Mr. WILLEMSSEN. Cost plus award fee.

Mr. DAVIS OF VIRGINIA. So it was won on price basically?

Mr. WILLEMSSEN. As I recall, yes. In retrospect, again, the contract was for requirements definition, design.

Mr. DAVIS OF VIRGINIA. OK.

Mr. WILLEMSSEN. Design, development and implementation. In retrospect one could say we might have looked at a requirements contract, which is appropriate for a cost plus environment, and then look at developing and implementing under a firm fixed price. That is something in retrospect that could have been considered.

Mr. DAVIS OF VIRGINIA. Let's go back to your observation of HCFA's management structure. Where does this fit into the reorganization currently going on at HCFA?

Mr. WILLEMSSEN. The reorganization is, I believe, expected to hit this summer. And as the chairman pointed out, there will be a chief information officer within HCFA so designated. We would obviously like to see that position take over much of the management and control of this project. We don't know yet—we don't have the details on whether that's actually going to occur. That could obviously be a question you want to pursue with HCFA.

Mr. DAVIS OF VIRGINIA. What if you were trying to take a look at today and say, what is it, was it $38.7 million that's been spent to date roughly? What has that bought us? Are we further down the pike from when we started, or do we really have to go back to the drawing boards, or we have some value for that?

Mr. WILLEMSSEN. I think we have some value and a better understanding of exactly what we think we want the system to do. There was a limited understanding of that up front. As depicted on the chart, we still don't have full agreement exactly on what those requirements are going to be. We're getting a little closer, but again, there was severe underestimation of the complexity involved, so we don't have that yet.

Mr. DAVIS OF VIRGINIA. So the underestimate was on the part of both the Government and everybody involved; is that right?

Mr. WILLEMSSEN. Yes, sir.

Mr. DAVIS OF VIRGINIA. I'm sorry, I didn't mean to stop you if you had anything else, any other observation on that. I think those are my questions at this point. And the project, how well-defined

was it when we started? Is that part of the problem as well, the whole project being defined?

Mr. WILLEMSSEN. Not well-defined because the first key element of it was to define requirements.

Mr. DAVIS OF VIRGINIA. Yes. OK. I got you. Thanks. I yield back.

Mr. HORN. Yes. The gentleman from Ohio.

Mr. KUCINICH. Is it in order? Do I——

Mr. HORN. I was going to turn to you next. I was going to get in a few questions here and then——

Mr. KUCINICH. I yield, of course.

Mr. HORN. OK. Let me just get in. It's one question with a number of parts, and that's looking at the fact that you've concluded that the transaction system is likely to reach $1 billion. Under the Information Technology Management Reform Act, which you mentioned in your testimony, the Clinger-Cohen Act, which came out of this committee last year, agencies must justify information technology expenditures through an investment review process.

Now, having said that, for nearly 4 years up until last fall, the Health Care Financing Administration justified its MTS expenditures by claiming $200 million per year in potential annual administrative savings.

Has either the Health Care Financing Administration or the General Accounting Office evaluated how much of these administration savings could be realized, or, in fact, has already been reached, simply by reducing the number of claims processing contractors or duplicative standard systems maintainers?

Mr. WILLEMSSEN. It appears that the data based on contractor cost reports for the years 1994 through 1996, do indicate that there is a reduction in claims processing costs on a unit basis. Neither we nor HCFA has gone into detail to explain the reasons for that reduction. That is something that we are recommending that HCFA do. As part of this interim environment, they may be getting benefits. We think it's especially important to track those benefits to see if, indeed, they are accruing, and they can compare those against the cost of the investment.

Mr. HORN. A substantial portion of these total savings promised by the MTS system might also be available from a far less expensive option. If so, wouldn't this undermine MTS's ability to meet the investment review criteria required by the Clinger-Cohen Act and the Information Technology Management Reform Act as it's called?

Mr. WILLEMSSEN. We're greatly encouraging HCFA to explore those other options, such as commercial off-the-shelf alternatives which may indeed be less costly; at the same time, may not give HCFA everything it wants, but that's part of the tradeoff that we have to look at in assessing alternatives.

Mr. HORN. Can the Health Care Financing Administration also realize program savings by focusing resources on waste, fraud and abuse software tools and incentives for the remaining contractors rather than building an entire MTS system? Is that an option?

Mr. WILLEMSSEN. That is definitely an option.

Mr. HORN. How good an option is it?

Mr. WILLEMSSEN. Well, again, I'm not going to sit here and tell you that they should do it. What I will tell you is that we think

they need to do the analysis and let that drive the appropriate decision rather than thinking—having a preconceived notion up front and then going with that and letting that drive the analysis.

Mr. HORN. I've got a number of questions here in that area, and I'm not going to take up time in the hearing room to do it. So you know our usual routine is for the joint staffs, Democrat and Republican, on both the subcommittees will be sending and following up with a series of questions.

I now yield to the gentleman from Ohio who had a comment to make.

Mr. KUCINICH. Mr. Chairman, I have had a chance to review here page 58 of the GAO report, critical unmitigated MTS risks.

And to the gentleman from the GAO, when you were first researching this, when was its earliest time you began this investigation?

Mr. WILLEMSSEN. We have done predominantly three separate reviews. This current assessment was started late last summer.

Mr. KUCINICH. And all of the impacts listed on table 4.1, each and every one of those impacts are things that exist now and into the immediate future, as opposed to something that you are commenting on existed and is now no longer a problem. These are current problems; is that correct?

Mr. WILLEMSSEN. Yes, sir.

Mr. KUCINICH. Who does the GAO use in its own realm of work for analysis of software and hardware?

Mr. WILLEMSSEN. Mr. Leonard J. Latham here is an expert in software development.

Mr. KUCINICH. Could I——

Mr. HORN. Certainly.

Mr. KUCINICH. Mr. Latham, was the problem in the development or in the implementation?

Mr. LATHAM. In the software, I think the problem started right from the beginning in a lack of being able to define requirements for the contractor to develop the code.

Mr. KUCINICH. Wait. To develop?

Mr. LATHAM. The software. The requirements need to be stable, they need to be well defined, before you can begin to address how you are going to achieve that requirement through a piece of software.

Mr. KUCINICH. Was the problem in the programming?

Mr. LATHAM. No, it was not in the programming.

Mr. KUCINICH. Was it in the code?

Mr. LATHAM. It was up front in setting requirements that would be used to develop code. They did not start coding immediately on the software.

Mr. KUCINICH. So if they didn't start coding immediately, the code was dependent on——

Mr. LATHAM. The code is strictly dependent, very dependent, on the up front analysis and identifying requirements, and writing those requirements in a form that the contractor and the programmers——

Mr. KUCINICH. By contractor, you mean?

Mr. LATHAM. GTE would be able to use to translate into a set of instructions for the computer to execute. Without those, they could not develop software.

Mr. KUCINICH. Right. And so was it the problem, the person who was doing the analysis really didn't understand the complexity of the system?

Mr. LATHAM. Well, I think what happened is, this has been a problem since the very beginning. GTE has been trying to help HCFA identify requirements from the beginning. At first, they started developing requirements and they returned some to HCFA; HCFA said they were too detailed; then they sent them back and redid them, and HCFA said it was not enough detail, then they said you just concentrate on integrating the future and current requirements to——

Mr. KUCINICH. And who did that part of it?

Mr. LATHAM. HCFA did that part of it basically.

Mr. KUCINICH. In house?

Mr. LATHAM. In house, they formed working panels and gab sessions, people who process claims in the various areas, fee-for-service and managed care, and they basically arrived at those requirements through those sessions. Those requirements were passed off to the contractor to form the basis for writing the code, the software, translating that into software.

Mr. KUCINICH. Mr. Chairman, in looking over this table 4.1, the critical unmitigated MTS risks, and reading the GAO's report about the impact that HCFA will be unable to assess MIS software development, difficulty in tracing requirements to MTS or Medicare functions, cannot assure the systems are interfacing appropriately, cannot assure the integrity of the management information systems products maintained, expected completion dates cannot be met—I am hopeful that in this recitation which GAO presents us with that there is going to be some way out of this morass. I guess the problem at this point isn't anymore who is responsible, it is who can help us straighten this out.

Mr. LATHAM. I think that is correct.

Mr. KUCINICH. Well, I'm asking you, who can help you?

Mr. LATHAM. I think HCFA needs to rely on its IV&V contractor to arrive at solutions and enlist the private sector contractor who can do those things. They could use the services of Carnegie-Mellon, who has developed a model to assess the weaknesses that there are in the software development process and bring together some mitigating controls to help them prevent problems.

Mr. KUCINICH. Mr. Chairman—and I will conclude with this discussion makes me wonder if people at HCFA took responsibility for the—essentially structuring the program, because they told GTE, look, we will handle it; who at HCFA was supervising that so that they could then take the responsibility and essentially not fulfill it.

And this isn't a matter of finger pointing, it is a matter of trying to understand why a system failed so that we don't repeat these problems, because it is possible that someone may have taken on a bigger challenge than they could have imagined. I mean, obviously, that is what happened, and that appears to be happening everywhere.

I just want to add an anecdote, even to the GAO, something as simple as a computer system with a local area network in a congressional office. Now hear this. I had a vendor who couldn't deliver. In my own office in Cleveland, we have had problems for weeks and months and have people in there right now, as we speak, trying to straighten it out. You wonder how many times this scenario happens across this country.

The whole idea of computerization is, we do things better and faster.

Mr. HORN. I might say to the gentleman, we all can empathize with his experience. I had one major firm, that will go nameless to protect the guilty, work 6 months in my office and not be able to get their system in, and we finally didn't pay them anything for 6 months, and they took it out, and we went back to our old system, which is a commentary on why I learned 10 years ago as a chair executive in the university that I always want to be the beta site, not the alpha site; let some other poor soul struggle through that. But we have repeated alpha sites in the Federal Government, and the question is, where is the learning curve?

I now yield to the gentlewoman from New York, Mrs. Maloney.

Mrs. MALONEY. Thank you, Mr. Chairman. We have a vote, so I will be brief.

We have another scathing GAO report. How would you rate this one compared to the IRS, the one you did on the IRS? Which is worse, IRS or HCFA?

Mr. WILLEMSSEN. I would say both are in the same ballpark.

Mrs. MALONEY. That's surprising, because in 1995 we had a hearing and HCFA testified we were on schedule and moving forward and everything was all right. And I just want to suggest, why don't we just go back to approaching it brick by brick, breaking it up, instead of trying to do everything in this one computer system, maybe taking it and taking one component, like we have started doing with the health care plan?

Instead of trying to come forward with a plan totally on health care, we are going brick by brick, taking children's health care, we are taking portability, issues like that. Why don't we take the various components of what we are trying to track to help you and break it down into manageable units instead of trying to do the whole thing at once? Maybe that could be something we could do.

And I just want to know, do you think we should continue with this contract, or do you think we should break it up into units, or should we just scrap this and start from the beginning? How do you get a computer system that works?

Mr. WILLEMSSEN. I think the critical steps that needs to be done is that HCFA should look at all available alternatives to accomplish what it wants to accomplish, and that is providing a more efficient information processing system that can better track fraud and abuse of the claims processing system, and, to date, HCFA hasn't looked at those other alternatives, such as commercial off-the-self options which may give them quite a bit of bang for the buck; may not give them everything they are looking for, but could be possibly implemented at a lower price.

Mrs. MALONEY. OK, that's a very fascinating recommendation, and, as you know, we have passed a procurement reform bill that moved to off-the-shelf purchases.

And I think you raise an important point too, which is, what do we do in the interim as we try to create a system that will be helpful to HCFA? What do we do in the interim on fraud and abuse and tracking and all the other things we are trying to do?

What might be helpful is if GAO came back to us with specific off-the-shelf items that they might be able to purchase right now that might track fraud and abuse, track the various components of what they are trying to achieve, and that maybe that could help them in the interim.

And I also would like a response in writing of probably breaking down the components; instead of trying to go into a computer system that does everything at once, if you took off one area and tried to solve that, and then another area, instead of trying to do it all together.

And, you know, what can I say? You can't get your computers to work.

Anyway, thank you.

Mr. HORN. Thank you. I believe we have already had a GAO report on the off-the-shelf programs, have we?

Mr. WILLEMSSEN. Yes, sir.

Mr. HORN. Certainly major insurance companies are using these now to check particular procedures that you are billed for, and I would hope Medicare is using them. Do we know if they are—go through what is checked off and say, gee, that doesn't make sense with a kidney operation?

Mr. WILLEMSSEN. May I defer to Mr. Latham on that?

Mr. HORN. Certainly.

Mr. LATHAM. I think, much to HCFA's credit, they have moved forward and are using a prototype of commercial off-the-shelf software at a location—I think it's one location, maybe more; I will beg off until I have those numbers—but to try to prototype the use of the software to see the kind of benefits they are going to be getting from it. I think the State they are using it in is Iowa; I'm not sure, but I think that's the first State.

They bought the package and installed it on one of the standard systems, and they are trying to basically observe how good or how well the software works in this fraud and abuse situation.

The problem seems to be HCFA's insistence, in order to use the commercial product, that they would have to significantly change their policies, because the types of edits that are in the commercial software basically are not in compliance with their particular policy on edits for particular services and benefits.

Mr. HORN. I thank you all for your testimony.

I can see, Mr. Willemssen, you have testified before us, while you have won the Meritorious Service Award from the General Accounting Office, and I thank you and both of your colleagues joining you to lay out the usual, very solid presentation. Thank you.

We will now move to panel two, Dr. Bruce Vladeck, the Administrator of the Health Care Financing Administration.

If you would raise your right hand?

[Witness sworn.]

Mr. HORN. Welcome. Please start. I have read your testimony. Mr. Davis will come back, and he will be acting chairman.

STATEMENT OF BRUCE VLADECK, ADMINISTRATOR, HEALTH CARE FINANCING ADMINISTRATION

Mr. VLADECK. Thank you very much, Mr. Chairman. We are pleased to be here today to discuss the Health Care Financing Administration's implementation of the Medicare Transaction System, which will provide a state-of-the-art platform for electronic billing and claims processing to meet the needs of Medicare beneficiaries well into the next century.

We all agree upon the common goal. Medicare needs to update its information technology capabilities. We believe MTS will provide a single, national, integrated information and transaction system that is central to our ability to meet our customer service and fiduciary responsibility.

As envisioned, MTS will be fundamentally an information system with a large payment processing component capable of adapting to changing needs. Our current claims processing systems are old and form a cumbersome and inadequate network with no integrated data base. Therefore, to solve problems, we must frequently access data bases, which is time consuming, laborious, and increases the potential for error. It is imperative that we make the transition to a new system as quickly as possible to continue to effectively serve Medicare and Medicaid beneficiaries.

MTS will provide the capability for timely information retrieval, introduce improved control over the distribution of benefit payments to comply with provisions of the Chief Financial Officers Act, process transactions more efficiently and for less cost, enhance our ability to detect and prevent payments for services that represent fraudulent or abusive billings, and dramatically improve customer service. Most importantly, MTS will have the ability to respond to the rapidly changing health care environment because of the modular nature of the system, which can plug in or modify systems as needed.

The development of the MTS system without disrupting service to providers is the largest task we have attempted. When the work began, we did not fully understand the enormousness of what we were undertaking. It is an exceedingly complex task, and as we continue through our re-evaluation process, we are refining our scope of work and comprehensive cost assessments. We welcome the assistance of this committee and others as we work to develop and implement MTS.

Some have asked us why we don't just update our current systems and build better interfaces rather than investing the time and resources to build MTS. This is analogous to asking someone with a 15-year-old computer trying to add memory and continue to repair it rather than taking advantage of new technology and buying a state-of-the-art model.

If we do nothing and stay with our current systems, we will still spend over the next 10 years approximately $20 billion processing claims and at least another billion dollars just maintaining current systems. The important point here is that through the use of supe-

rior technology, MTS can change our focus from paying claims to meeting program needs.

We appreciate the comments of the General Accounting Office and others who have advised us in the management of the MTS initiative, and we realize the formidable challenge we face in making the transition without adversely affecting our beneficiaries while continuing to process almost 1 billion claims a year. This workload is added to ongoing activities such as implementation of Operation Restore Trust and the Medicare Integrity Program and the turnover of Medicare contractors.

Let me emphasize that we would be the first to admit that the task is more complex than we originally contemplated. During the past 3 years, we have learned how best to identify the type and level of system requirements necessary for MTS and how to improve the management of the program. The assistance provided by our IV&V contractors and others has been invaluable and has redirected our software development approach by breaking down the project to multiple phases or releases, resulting in reduced risk and incremental implementation and more thorough testing of each component.

Mr. DAVIS OF VIRGINIA [presiding]. You were trying to get through before anybody got back to ask you any questions.

Mr. VLADECK. Now that you are here, I would be happy to stop with the statement. I had to keep talking until one of the Members appeared. Should I continue?

Mr. DAVIS OF VIRGINIA. Sure.

Mr. VLADECK. Recognizing the importance of managed care in Medicaid's future, we have clarified the contract in this area and given it priority as the first release——

Mr. DAVIS OF VIRGINIA. I will tell you what. We will enter that in the record and go right to the questions.

Mr. VLADECK. Can I say one thing for the record, because I need to correct something in the written testimony and I would like to read it into the record if I can? It was on, I don't know what page, on some of the budget numbers. They need to be updated and corrected slightly.

As of March 31, 1997, the testimony we submitted to you said that we had spent $43.4 million. The correct figure is $43.5 million. There is also a flat out typo in terms of total money obligated in all MTS related contracts. The testimony reads "$110 million." That should have been "approximately $101 million," and that is purely a typo. And I would like to have both of those corrected in the record, if I may. The rest will be submitted for the record.

Mr. DAVIS OF VIRGINIA. Without objection, the rest will be entered in the record.

[The prepared statement of Mr. Vladeck follows:]

INTRODUCTION

Good morning, Mr. Chairman and Members of the Committee. I am pleased to be here today to discuss with you the Health Care Financing Administration's efforts toward implementation of the Medicare Transaction System (MTS), which will provide a state-of-the-art platform for electronic billing and claims processing to meet the needs of Medicare beneficiaries well into the next century.

Our current claims processing systems are old and do not provide us with the timely information we require as prudent stewards of the Medicare program. Moreover, the 8 operating systems --- with 70 contractors at 34 data centers --- form a cumbersome and inadequate network with no connections between fee-for-service systems and databases and those for managed care. In addition, components of the Common Working File, the primary database for beneficiary and provider information, reside at nine separate sites.

We all agree upon this common goal: Medicare needs to update its information technology capabilities. We believe MTS will provide a single, national integrated information and transaction system that is key to our ability to meet our customer service and fiduciary responsibilities into the 21st century. MTS represents the largest infrastructure change ever undertaken by HCFA, and it is critically important to meeting HCFA's business goals For these reasons, we are committed to the completion of the MTS project.

As envisioned, MTS will be fundamentally an information system with a large payment processing component capable of adapting to changing needs. MTS will integrate Medicare Part A, Part B, and managed care data and increase the standardization of Federal data requirements and payment policy; amplify detection of program fraud; enhance the coordination of insurance benefits so that we can ensure that Medicare pays only when it is supposed to; increase access to electronic data; and provide Medicare beneficiaries and providers with a single point of contact to resolve all program inquiries. This will not be a monolithic computer system but a modular system that will be tested and implemented incrementally in order to reduce risk.

As I mentioned, HCFA's current processing environment links dozens of contractors operating eight different systems to HCFA. The system has evolved into a patchwork of redundant and antiquated systems and interfaces that have developed over the past 30 years, and it is incapable of providing timely and accurate information because no integrated database exists. Therefore, to resolve simple problems, we must frequently access various databases, including those of our intermediaries and carriers, the Common Working File, SSA's, and HCFA's own internal databases.

It is imperative that we make the transition to a new system as quickly as possible, to continue to serve our Medicare and Medicaid beneficiaries MTS will provide the capability for timely information retrieval, introduce improved control over the distribution of benefit payments to comply with provisions of the Chief Financial Officer Act, process transactions more efficiently and for less cost, enhance our ability to detect and prevent payments for services that represent fraudulent or

abusive billings, and dramatically improve customer service. Most importantly, MTS will have the flexibility to respond to the rapidly changing health care environment because of the modular nature of the system, which can "plug in" or modify functionality as needed.

The development and implementation of MTS, without disrupting service to beneficiaries, is the single largest task HCFA has attempted. When the work on this system began, we did not fully understand the enormity of what we were undertaking. It is an exceedingly complex task. As such, we are currently in the process of reevaluating the implementation design for MTS. As we continue through this reevaluation process, we understand more of the issues and influences and will be better prepared to specify more details. This has implications for scope of work and what the ultimate costs of MTS will be. We welcome assistance from Congress and others as we labor to get the best possible Medicare Transaction System.

Some have asked why we don't simply update our current processing systems and build better interfaces, rather than investing the time and resources to build the MTS. This would be akin to someone with a 15 year old computer, trying to add memory and continue to repair the computer, rather than taking advantage of new technology and buying a state-of-the-art model. The old computer would never be able to do what the new one would, no matter how much memory was added. Similarly, repairing and "updating" our current processing systems will never give us the timely information we require. The important point here is that MTS changes Medicare's focus from paying claims to meeting the needs of our beneficiaries.

The General Accounting Office, among others who have advised us on MTS, has emphasized the importance of HCFA's integrating MTS project management with our current operating business goals. We agree. The challenge for HCFA, as we see it, is not just to design and build a new system, but to do it without increases in staff and without adversely affecting our beneficiaries or their providers of health care while we process over a billion claims per year.

To further complicate this scenario, HCFA's workload has increased as we have addressed critical operational issues. These include replacing the unanticipatedly large number of Medicare contractors deciding to leave the program due to their own business interests, implementing new initiatives to address program integrity such as Operation Restore Trust and the Medicare Integrity Program, and coping with changes needed as more and more beneficiaries enroll in managed care organizations.

Let's look at this from a different perspective. If HCFA were to do nothing --- and stay with our current systems --- we would still spend over approximately $20 billion over the next 10 years processing claims and at least another $1 billion in maintaining current systems. And that doesn't account for the as yet unknown changes that will certainly occur in the Medicare program, in the health care industry and in insurance markets. Further, at the end of that period we would have to face the reality that current methods of processing transactions and information are simply not adequate to serve our beneficiaries and providers, nor are they capable of providing the nation's health policy makers the timely and relevant information necessary to make informed decisions on critical public policy issues.

MANAGEMENT OF MTS

Although we are steadfast in our belief that HCFA must make the changes in information technology represented in the MTS initiative, we admit the task is more complex than originally contemplated. For example, it took us some time to understand how best to identify the type and level of system requirements necessary for MTS. We have learned a great deal in the last 3 years about ways to improve the management of complicated technology projects, and GAO and others have been of significant assistance in offering suggestions for improved management.

We have benefitted significantly from outside oversight of the MTS project. The recommendations we received have often affirmed our internal decisions. For example, we revamped our approach to MTS to support the software development in multiple phases or releases. This breaks the project down into more manageable segments of work, reduces risk, and allows for an incremental implementation of successive pieces of MTS. This approach also permits a more thorough testing of each MTS component to work out the bugs before implementation of the next piece of the system. Compared to a "big bang" approach, where all pieces start simultaneously on day one of MTS, incremental implementation of MTS is a more prudent approach.

Because we recognized that we did not have the all the expertise we needed internally, HCFA sought contractual assistance early on from top-notch management consultants on critical project issues, including managing risk; consolidating and integrating systems; timing and scheduling of project phases; building, using and testing hardware and software; planning transitions; and utilizing resources. We also have received invaluable advice from our independent verification and validation

contractor. With help from all of these sources, we recognized the need for flexibility as we reassess our MTS development strategy.

Last fall we modified the contract of our software developer, GTE, to add work to clarify the role of managed care in the MTS. Unlike fee-for-service claims, which are paid by our contractors, HCFA pays Medicare HMOs directly, using an in-house system that is more than ten years old and inadequate to meet its growing workload.

The increasing trend towards managed care is an important factor in Medicare's future, but it is also an immediate business need in serving a growing number beneficiaries and health care plans. The managed care piece of the system is so important to HCFA that we gave it priority as the first release to be provided by GTE.

No project of the complexity of MTS can be accomplished without difficulties. We recognized the need to build processes to better ensure early disclosure of marginal performance. During the contract renegotiation last summer, GTE agreed to the inclusion of performance metrics to measure their progress in accomplishing project tasks. In March, our evaluation of the performance measures indicated that GTE was slipping increasingly behind schedule, with the consequent potential for significant cost overruns. Our decision to stop work on all areas of the contract, other than managed care, and to reassess our MTS development strategy are examples of aggressive project management and our willingness to intercede.

REASSESSING THE MTS STRATEGY

We announced our decision to reassess our MTS strategy on April 4. HCFA has set a timetable of no more than 90 days from that date to review contingencies and develop plans for the future. During this period, we are continuing to monitor GTE's work on the managed care module very closely. GTE's efforts are progressing from developing more detailed systems requirements to coding and testing , and HCFA already has performance measures in place to assess this phase of activity to ensure that GTE meets time, schedule, and quality goals. By the end of the 90-day period, we will decide what GTE's future role will be in the MTS project. We are also working with a group of Federal employees who are expert in systems design and project management. This group, the Information Technology Resources Board or ITRB, is assisting us in reassessing the MTS design and implementation.

In addition, we are evaluating other alternatives for moving forward with MTS, considering more incremental development approaches and different partnering arrangements, examining their technical feasibility, relative strengths and potential risks. We will incorporate an examination of the return on investment as part of our analysis. This does not mean that our vision for MTS is changing. To achieve our shared goals, MTS must still provide the integrated databases needed to strengthen payment safeguards, comply with the Chief Financial Officer Act, improve customer service, and achieve administrative efficiencies. No later than the beginning of July, we expect to have a plan and strategy for moving ahead with MTS.

WORK ON MTS-RELATED ACTIVITIES CONTINUES

In the meantime, HCFA is continuing to work on activities that are critical to moving forward with MTS and to help Medicare fiscal intermediaries transition to a single part A claims processing system. In fact, we have completed the transition of all intermediaries on one of the old software systems to the new standard system. We have a schedule for the remaining Part A transitions and will begin transitions from a second old system this month. HCFA recently awarded a contract for the single part B system and is currently planning for the transition of Medicare carriers to this new system to begin shortly.

Over the last 3 years, we have gained extensive experience in transitions as we replaced contractors that left the program. We are now able to make these transitions smoothly and successfully. We are also working under an interagency agreement with Los Alamos National Laboratories to model the best approach to transitions given the resources available.

LOOKING AHEAD TO YEAR 2000

HCFA is also preparing for systems changes that are necessary for the year 2000. Changes have already been accomplished in critical areas that required urgent attention. With or without MTS, HCFA will be fully prepared to process payments on January 1, 2000. HCFA's Millennium Team has assessed the risk to current systems and prioritized action that needs to be taken. A specific workgroup is addressing technical issues such as standards, algorithms, bridge software and coordination among Medicare contractors, standard system maintainers, external users, and data suppliers.

Beginning two years ago, additional funding was provided to Medicare contractors for necessary system changes to be able to continue uninterrupted claims processing. HCFA has also designed a data collection system to track changes being made and assist in coordinating millennium changes between systems. Our regional offices are coordinating and overseeing the millennium effort for our contractors in the field.

MTS COSTS

Finally, I want to address the cost of the MTS initiative. There has been much discussion of what the total cost of MTS will be and when those dollars will be spent. Unfortunately, each discussion has focused on different "slices" of the costs, estimated at different points in time. Before discussing the numbers, I would like to stress the complexity of the MTS cost analysis, which includes the cost of maintaining and continuing to operate an existing system while building a new one around it.

Both GAO and HCFA estimate that the total cost of implementing the MTS will be nearly $1 billion over ten years. This estimate could change based on our new design approach. In addition to the design and development costs for the project, this estimate includes the cost of moving from the current environment in which 8 processing systems operate independently, to a single processing system each for Part A and Part B, before moving to the new MTS structure. And the cost of a year of claims processing with the new MTS software is also a part of the investment. As we settled on the design for the MTS, and as the scope of the project has become clearer, we have refined our estimates to include this total project effort over the next 10 years. When we complete our evaluation of alternative MTS implementation strategies, we will be able to estimate the cost to complete the

project, and provide a model that projects the out year MTS investment.

Let me provide the cost of MTS development to date. As of March 31, 1997, we had incurred costs of $43.4 million -- $38.7 million for GTE's work , and an additional $4.8 million on independent evaluation of GTE's progress, support in testing software, and systems integration. (A total of approximately $110 million has been obligated for these contracts so far.)

The $38.7 million for GTE's work has not been wasted. There have been substantial gains from the GTE software development effort. GTE has completed fully-developed systems specifications for handling managed care payment processes as well as enrollments and disenrollments, a high-level systems design, an operating systems infrastructure, a solution for data security, as well as an analysis for the functional requirements for Phase I of the MTS system. If we were to terminate the contract, HCFA would own the products and benefit from the analysis and development already completed.

HCFA's in-house personnel, travel, and education costs for MTS for fiscal year FY1996 were $6.4 million and for FY 1997 were estimated at $7 9 million, less than one percent of HCFA's yearly administrative costs. The reassessment of our MTS strategy could affect future in-house costs, a factor which we will consider as we review alternatives

In addition, we have spent $7.9 million in FY 1996 to convert workload to the standard Part A system. We project that we will spend an additional $62 3 million in FY 1997 for conversions to the single Part A and Part B systems.

The President's FY 1998 Budget requested $89 million for MTS. The bulk of this would be spent on continuing to transition contractors to single Part A and Part B systems. The remainder will be spent on the test facility and independent verification and validation activities.

GAO has used the 1992 estimate that HCFA prepared for a GSA procurement delegation to assert that the cost of the MTS program has increased eightfold --- from $151 million in 1992 to $1 billion in 1997. I would like to speak to that comparison. We agree that estimates need to be constantly refined and compared, however, we consider comparison of the 1992 estimate to the present to be like comparing apples and oranges. The estimate of $151 million was a beginning best guess to get the project underway. At that stage, it was not possible to price a systems strategy that had not yet been developed or selected nor did it include risk mitigation efforts that were initiated later as the complexity of the project became more clear. For example, one of the biggest cost drivers is the transition strategy to single Part A and Part B processing systems; however, this strategy is also one of the best means of risk mitigation. This transition strategy, which was not part of the original MTS strategy, has been estimated at over $350 million over 10 years. The cost of obtaining data processing capacity for MTS was also not included in our FY1992 estimates.

OVERSIGHT OF MTS

For the last two years, the MTS project has been the subject of intensive oversight - not only from the General Accounting Office and Congress, but from other Federal agencies and private industry. As you know, recently enacted legislation gives the Department's Chief Information Officer specific oversight responsibilities. The oversight of the MTS project involved not only HCFA, but also our

contractors working on the MTS project and the Medicare contractors currently processing Medicare claims.

The very clear and consistent message from this oversight was the absolute necessity of avoiding budgetary risks. We are acutely aware of the public responsibility inherent in the investment of public funds, and that is, in part, what drives the MTS project. Our preliminary return on investment analysis shows that unless HCFA's systems are modernized, the public will continue to pay more than necessary for the administration of Medicare, and program payments will continue to exceed what is necessary and reasonable.

I am fully aware of the need to constrain Federal spending. The President has put forth a proposal to balance the federal budget in 2002 that would reduce the growth of spending in Medicare. Currently, we spend more than $500 million per day on services for beneficiaries. At this point in the MTS project, while we must focus on minimizing budget risk, we must not compromise our ability to minimize program risk. We must move forward with confidence that we have invested adequately to get the job done right.

We need to keep these considerations in mind as we continue to reassess our MTS development strategy. The safest course, in terms of minimizing budgetary risk, may not be the most prudent. Risks associated with the MTS development process must be weighted against the very significant potential gains.

When you come right down to it, MTS is an enormous undertaking, it's extremely complicated and not without risk. But this is true of all systems projects of this nature. The important point is that risk can be managed and mitigated, and we believe HCFA, with all the appropriate assistance and oversight of others, has demonstrated its ability to do that.

The bottom line is that the MTS vision is the right vision for the Medicare program. To do other than continue with MTS development would be to renege on our obligations to our beneficiaries and the nations's taxpayers. And we would be sorely tried to meet future challenges inherent in our rapidly changing health care environment. We need to do more, we need to do it better, and we need to do it faster. We need to seize this opportunity to build on past experience, invest the dollars realistically necessary to develop and implement the system, and take the risk - albeit wisely and with reasonable plans to ensure success.

I look for your support as we move forward with this critical project. Your concerns, suggestions, and assistance are all welcome expressions of our need to work in partnership to see the MTS project through to a successful conclusion.

Mr. DAVIS OF VIRGINIA. Let me ask, do you see the chart up there, the volatility of MTS requirements? What happened in January 1997, that brought the requirements down so low?

Mr. VLADECK. The only version of the MTS report that I have, the GAO report I saw was a fax version that was not entirely clear. But you have to understand that prior to early 1997, all requirements or projections are estimates, based on what is very much a work in progress. In fact, requirements for releases 2 through 5 have not yet been completed; GTE has just completed work on requirements for release 1.

So all of the numbers are projections of estimated future requirements, and as the project has proceeded, those requirements have evolved and those estimates have changed and evolved over time.

Mr. DAVIS OF VIRGINIA. I understand that, but you go to 1/97, and in all but one of the charts it is at a low point. Is there any explanation for why at that point it was—do you see what I am saying?

Mr. VLADECK. Yes, and the only thing I can say is that for release 1, the February 1997 date is near completion of the specification requirement work.

So the only observation I can make is, all of the rest of these charts reflect estimates associated with work that is still very, very much in progress. I think we estimated then February 7 the requirements for release 1 were about 90, 95 percent completed, and we had the most solid numbers associated with that.

Mr. DAVIS OF VIRGINIA. OK. I wonder if you would identify the HCFA activities which will ensure that the interim operating environment is being well managed. You heard GAO suggest that detailed planning is lacking, and I know you are trying to ensure that the current claims process remains uninterpreted while the additional systems are integrated, at the same time addressing the year 2000 issues. What is going on?

Mr. VLADECK. Let me say two words about that, if I can, and about the management of the overall current environment, and then let me speak specifically to the year 2000 issue.

The issue of the current environment is something of a euphemism, if I may, for the existing relationships we have with approximately 70 contractors. Those relationships are changing all the time, often in ways that are not entirely within our control.

For example, one of our largest contractors since the beginning of the Medicare program was Aetna, which about a year ago undertook a merger with U.S. Healthcare and then decided 3 or 4 months thereafter that they no longer wanted to be in the fee-for-service business, including the Medicare claims processing business. So we all of a sudden were confronted with the need to convert the very, very large workload associated with Aetna to other contractors.

We have in place some very well-specified and well-established routines and plans for dealing with contractor transitions, when one contractor leaves, distributing the work. We have contingency plans with most of the large continuing contractors.

For Part A, the Blue Cross Association still has a statutory master contract for which individual plans for subcontractors, and we work regularly with them. But there is an inherent unpredict-

ability and inability to plan in any formal document that is associated with that activity.

The second issue is the transition from the three standard systems on Part A and five standard systems on Part B to a single Part A and a single Part B system. We have a very detailed project management plan for the Part A transitions, and we have already completed the switchover of one of the nonsurviving Part A software systems to what will become the standard system.

We have also contracted with Los Alamos National Laboratories for some very specific sorts of project management and project tracking software to help give a little bit more formal structure and a little bit more external accountability to the management of all of these transitions over the next number of years. The beginning pieces of that Los Alamos work is already beginning to be incorporated into our system management.

On the year 2000 issue, we began about 18 months ago to work with our existing contractors to address the year 2000 issue. To date, they have all identified for us, and we have reviewed their work in this regard, all of the lines of code that will need to be rewritten in order to be year 2000 compliant. We have agreed on standard formats and standard solutions for the implementation of the new codes. Our contractors have all given us schedules to rewrite all of the relevant lines by December 31, 1998, and we are tracking their progress, actually doing that coding rewrite on a quarterly basis for each contractor.

Now, we had thought at one time that since we are transitioning to standard systems, we might just want to focus on making sure that the standard A, standard B, and standard durable medical equipment software was year 2000 compliant and not worry about the systems we have hoped to phaseout before then. But we have taken a little bit of a belt-and-suspenders approach to that, so we are taking the time to rewrite all of the necessary lines of code even for those systems we will be phasing out probably before the year 2000.

And I think if GAO were to come back and revisit our status of the management of that particular issue at the moment, I think their comments on that specific issue might be more favorable than they were in the report they provided to you.

Mr. DAVIS OF VIRGINIA. OK. At what point did HCFA modify its original cost estimate of $150 million for the MTS project to reflect the transition costs, administrative costs, and costs due to the underestimates of the MTS project?

Mr. VLADECK. The $150 million estimate was never our estimate for total systems development and implementation cost, but we have provided the committee recently, for example, a long-term cost-benefit model for implementation of the system which we prepared in November. That was the fifth such cost model that we have prepared since the inception of the project in 1993, 1994.

We are going to need to revise it and update it once we have completed the reevaluation of our systems development strategy over the next 6 or 8 weeks. But part of the issue has been that as the implementation strategy has evolved, what goes into the particular cost model has changed over time.

And so I would say that the big change in terms of the evolution of our estimation of the cost of the product came when we got the systems design architecture documents from GTE and went back and forth with them and accepted the documents. Those identify the need for a test facility and began to specify some of the hardware requirements associated with full implementation, some of the telecommunications requirements associated with that in a way that we had never before been able to identify because we never had an overall systems design.

Mr. DAVIS OF VIRGINIA. I was just trying to aggregate the transition costs, and I am having a hard time because we have a lump sum here. Could you help me with that?

Mr. VLADECK. Which transition costs over which period?

Mr. DAVIS OF VIRGINIA. This would be the total costs over the time—particularly as you look at it, it looks like the 1988—1997, 1998, 1999 timeframe when the costs are estimated increasing significantly.

Mr. VLADECK. Well, we estimate, I think, the total transition costs associated with the President's budget for fiscal 1998 are approximately $80 million, if I'm not mistaken, compared to $50 or $60 million in the current fiscal year.

And I would have to check with my staff on what our projections are in the transition numbers in the following fiscal years. I think we are running in the range of $75 to $100 million per year through the next 4 or 5 years for transitions either of contractors leaving the program and switching their workload and for the transitions of the obsolete A and B systems into the new system.

Mr. DAVIS OF VIRGINIA. OK. To date—I asked this question to GAO—what do you think the $38.7 million spent for GTE's work on the project has purchased us so far?

Mr. VLADECK. Well, it has gotten us a basic systems design; it has gotten us a set of requirements, plans relative to communications and relative to security in the telecommunications network; it has gotten a design for a test facility; and we believe it has just about completed the requirements portion of the work for writing the new release 1 for a new managed care claims processing system.

Mr. DAVIS OF VIRGINIA. And that has cost us $38.7 million. What is that worth?

Mr. VLADECK. I can't answer that question. I don't have a sense of what a market price of that would be. I think in the context of what we spend on maintenance of the current claims processing system in a given year, I think it represents some progress, but I think it will have to be further down the line in terms of development of the system before we can look back and say, was that $38 million worth; $50 million worth; $25 million worth? I couldn't answer that question any better.

Mr. DAVIS OF VIRGINIA. All right. We saw earlier warning letters going back a couple years from the IV&Vs noting there were some problems. At what point did HCFA realize that the contract had incurred substantial cost overrun? Whom did you advise at that point?

Mr. VLADECK. I think we really began to identify problems in the cost part of the contract probably in early 1995, and—or mid-1995,

and we began at that point to discuss with them modifications of the project to talk about reallocation of responsibilities on the requirements between ourselves and them.

We didn't really get to beginning to discuss a renegotiation of the contract relative to these cost issues and so forth until the very early part of 1996, and we then spent about the first half of 1996 in negotiations with them over modifications to the contract.

During that period of time, I guess some of the other folks involved in information technology management within HHS were aware of that. I don't know the extent to which they shared that with folks in OMB.

In addition, at some point in the spring or summer of 1996, the GAO became aware of it as part of our discussions with them as they were conducting their reviews of the project management.

Mr. DAVIS OF VIRGINIA. OK, I think my time is up. Mr. Chairman, I yield back.

Mr. HORN [presiding]. Thank you very much.

You might have discussed this when I was out of the room voting, but let me pursue this since I have read your statement. I'm curious, in the 90-day review during which the Health Care Financing Administration is reviewing its options for MTS, will you be considering both the cost and the savings associated with each option?

Mr. VLADECK. We will be, although the issue on the savings is less a question of estimating what the savings might be as when they will be attainable.

The real complicated part of a cost-benefit analysis on the MTS has to do with the timing of incurring of expenditures as opposed to the realization of savings. I don't think we will be making a lot of effort to re-estimate what the steady State level of savings is at completion of the project. The question will be trying to estimate when those savings streams will become available in terms of development options.

Mr. HORN. I don't know if you were in the room when I asked the General Accounting Office the degree to which commercial software that insurance use to check some of their bills against particular operations—let's say you have got a kidney operation; there are certain characteristics of that before, during, and after. Would it have been better if your administration had taken a look at those existing commercial software packages?

Mr. VLADECK. Well, as the witness for the General Accounting Office said, we are testing one package in Iowa at the moment. I would like to amend slightly what he said about that, however.

The problem we have had using the commercial software, which is the problem we anticipated, is that we have to modify the commercial software to meet Medicare rules. These are not arbitrary software requirements or computer programming rules, these are statutory or regulatory coverage rules which are part of the Medicare program which, in many instances, are different from those that apply to private health insurers.

So while it is, in a sense, an off-the-shelf product, it turns out it requires a significant amount of customization in order to be consistent with Medicare rules and policies. That process is just about

complete, as I understand it, and we will begin the test and ought to have results from it in the next 3 to 6 months.

Again, that is one particular example of the software, but it is also being used with one particular existing standard system of software, and the extent to which we would have to customize it again to apply it to existing systems is one that we are now looking at but about which I can't yet give you an answer.

Mr. HORN. On the 90-day review process, if a less ambitious option could achieve a substantial portion of the savings, would this 90-day review result in such a finding?

Mr. VLADECK. Absolutely.

Mr. HORN. When will you share the analysis of costs and savings with our respective subcommittees and any other authorization committees of the Congress, as well as with the General Accounting Office?

Mr. VLADECK. We expect this process to be completed in about the first 10 days to 2 weeks of the month of July, and within 10 days to 2 weeks of the completion of the process we would expect to be in the committee's offices reviewing our analyses with your staff and whoever else wanted to participate.

Mr. HORN. Well, I thank you, and I'm delighted to yield 10 minutes to the ranking Democratic member on the full committee, and I am sure he has a number of questions.

Mr. WAXMAN. Thank you.

With all the problems you have experienced with MTS, are you still convinced MTS is the right thing to do? And can we still expect a system that will bring the benefits you hope for in finding fraud and abuse and making the Medicare system work the way we want it to work?

Mr. VLADECK. Mr. Waxman, we have no question, based on some of our custom-tailored additional expenditures we have had to make, for example, as part of Operation Restore Trust, where we have had to take Part A data and Part B data from a State and merge it with Medicaid data at enormous expenditure, but once we had that merged data base, we were able to do a number of really neat things in terms of detecting fraud and abuse.

So if we ever get our system to the point where we have on-line A and B and can integrate it with data from other entities, such as Medicaid, we know, based on our experience from the past couple of years, that will have an enormous benefit on behalf of the program integrity side.

But I want to emphasize as well, because it tends to be overlooked, that there are very, very important customer service implications for this as well, some of which have very programmatic savings, and I would like to give my favorite example, if I can.

As all of you know, the nightmare associated with every Medicare beneficiary is the shopping bag full of pieces of paper, each of which says, "This is not a bill," which are the explanation of Medicare benefits which we now mail out every time we process a claim to every beneficiary and which then often, depending on the supplemental or medigap insurance the beneficiary has, generates two or three additional pieces of paper in correspondence with the supplemental.

We are already field testing what we call a Medicare Summary Notice, which is a single one- or two-page document modeled on the credit card or department store monthly billing statement, which can incorporate all of the claims information that a beneficiary has in a given month.

Now, for Medicare only because our ability to electronically integrate the supplemental carriers is limited, but when MTS is up and running we will be able to have that integrated file for both Parts A and B and supplemental insurance. Our beneficiaries will get a single statement every month of the claims that have been incurred, what we paid, what their co-payment obligations might be, what their supplemental carrier paid, and so forth.

We think that will be an enormous improvement in terms of customer service. Not inconsequently, at the price of 32 cents postage if we are mailing 300 million of these statements a year to beneficiaries, as opposed to 1 billion EOMBs a year, we are saving a couple million dollars in postage as a result of that improvement in our capability.

So that's one example on the customer service side. There are major, major customer service implications. Everything is in place except the underlying data processing capability at the moment.

Mr. WAXMAN. And, of course, if you are able to have a computer system track fraud and abuse of the system, that can also lead to enormous savings of dollars, because I think a lot goes to fraud and abuse in the system.

Mr. VLADECK. Our actuaries have estimated conservatively that the ability of the kind of data base that MTS would permit, as well as being able to plug in commercial fraud detection software, conservatively, would save us in program expenses and trust fund outlays half a billion dollars a year every year after the implementation of this system.

Mr. WAXMAN. Thank you.

Looking at the existing law where you have 40 different processing sites you have to pay if there is any termination of a contract, have you looked at any recommendations for us that would help you hold down some of the costs?

Mr. VLADECK. Well, as you know, Mr. Waxman, as part of the health insurance portability legislation last year, we were given new contracting authority relative to the program integrity functions in the Medicare contracting system which also gave us some new ability to reach out to new kinds of contractors and establish relationships with those contractors under general Federal procurement law rather than under special title 18 provisions.

We are learning how to use those authorities at the moment, and if we have the kind of experience we look to have, then I think we would probably want to be back to you to talk about further changes in the law as relates to Medicare contractors.

Mr. WAXMAN. Mr. Chairman, we are serving a very important purpose for the Congress, and that is oversight over taxpayers' money, and we have seen in a number of different instances, where we have attempted to move into huge computer systems, a lot of money spent without much gain for it. And we are serving an important purpose, and GAO is being very helpful to us in analyzing how well we are doing in this regard.

I hope that, Dr. Vladeck, this will be a very constructive way for us to all figure out the best way to come to the realization of a system that will accomplish what could be so important for Medicare, the integrity of the Medicare program and the benefit to the Medicare beneficiaries to get the kind of information that we hope the system will provide.

It is a frustration for all of us to see, like in the IRS and other areas, high hopes not being realized. So any suggestions you have or talking to GAO could recommend to us, I know the chairman of our subcommittee—and I want to work with him—wants to be as helpful and constructive as he possibly can.

I thank you, Mr. Chairman, for your leadership for holding this hearing and yielding the time to me, which I yield back to you.

Mr. HORN. I thank the gentleman, and we are delighted you could come to the hearing.

I yield to the gentleman from Texas.

Mr. SESSIONS. Good morning—I guess it is afternoon already. When you haven't had lunch yet, you tend to call it morning.

I would like to direct you to page 4, and I will be candid with you, I have not had an opportunity to read or review this. It is just now evidently available today. But it talks about results in brief, and I am not going to ask you to defend or deny anything that is here but, rather, to discuss it with some objectivity if you could.

In particular, I would like to take you to the second paragraph, and I will read: "Further, HCFA is relying on its Medicare systems contractors to assess, plan, and implement essential changes for the year 2000 issue, but it is not closely monitoring these critical activities or receiving certifications or assurances from contractors that the problems will be corrected."

Mr. VLADECK. Mr. Sessions, as I think I said earlier, we found much in the GAO report quite helpful, but I am frankly—this particular assertion I frankly find kind of puzzling, because I believe—and maybe it has to do with the time of when the GAO looked at particular parts of our system—we are, in fact, monitoring the work that our contractors are doing on addressing the year 2000 problems on a quarterly basis. We are checking their testing of some of the new code they are writing and so forth.

I think there are many legitimate criticisms of us in the course of this report, and I think some of the broader questions that the GAO raises are recommendations that they make about the way in which we manage the transition of our current system to a future system. We have very much taken them to heart.

But I almost feel a little bit of a catch–22 on this particular criticism, if I may, for the following reason. One of the reasons we have always said we need an MTS system is because we have all these different software systems out there which we don't own, and some of which are proprietary. Part B bills are paid in some parts of the country by proprietary systems the Government doesn't even own. Once we have MTS, we will have a system, and after the next crisis is after the year 2000 crisis, we will have one set of software under the Government's ownership and the Government's control, and we can bring in all kind of folks to look at that and work on that and fix the system once.

Under the existing systems, we have these eight sets of software, some of them proprietary, each of them customized, which are owned by our contractors or shared contractor providers, and each of them needs to be rewritten. That's sort of a demonstration of why we need MTS.

But the fact is, we are sitting on the process of the actual line-by-line code writing that the contractors are doing. We have provided them additional budget dollars with which to do it; we are auditing those expenditures; and, again, of all the assertions in the GAO report, this is the one where I think we would most take issue with the facts.

Now, again, they have been working on this a long time, and there may be a timing issue.

Mr. SESSIONS. Well, the reason why I bring this up, this is, as you know, the Y2K problem; and it is universal, it is not you; it is a show-stopper. Are you telling me that you have your hands around the project, that at the year 2001 you are not going to have a show-stopping incident within this system?

Mr. VLADECK. Well, I have learned never to say "never." We have a plan for the claims process, and we have a number of other projects, Y2K updates as well, and we are working on it and have a detailed plan for working on it. But basically we are not under as much scrutiny on some of those.

Mr. SESSIONS. You are not under scrutiny or not putting your contractors under——

Mr. VLADECK. We are not putting ourselves under as the contractors on the basic claims processing.

So let me say this to you, because I think this is the appropriate way to answer. We have required of all the Medicare contractors that they have completed their year 2000 corrections by December 31, 1998. We will have the first part of 1999 to do extensive testing on the extent to which they have in fact achieved, accomplished, those changes.

I have a high degree of confidence that we will be there with some time to spare, but we have left in a cushion because nothing ever goes perfectly, and for a problem of this magnitude we want to know that we have thoroughly tested it, and we will have a number of months to find and test the glitch that will undoubtedly—I have a paper here, we're talking about the actual rewriting of 12 to 15 million—more than that, something like 20 million lines of code, of software code. And again, we have detailed work plans for that. We think we have identified the lines of code that need to be rewritten. We have budgets and plans to do that over the next what would be 19 months.

But we are going to extensively test all that revised software after it has been rewritten, and, with 20 million lines of code, somebody is going to mess up somewhere, and we will find things in the testing process. But we will find that in late 1998, early 1999, not on December 31.

Mr. SESSIONS. Or at least that's your plan.

Mr. VLADECK. That's our hope and plan.

Mr. SESSIONS. For the sake of my discussion here, trying to be a reasonable and logical person, could you please, within a reasonable time after going back to your office, please respond back to

this paragraph, this last statement. You are saying to me that you don't really know when the GAO looked at that and received that snapshot of an idea. You now think you are beyond that. Obviously, GAO is going to come and comment on this. I would like to have your latest analysis that you could have provided them had they done this snapshot today that simply addresses not the larger picture but the smaller issues and how you would have responded.

Mr. VLADECK. We will be happy to.

Mr. SESSIONS. It will avoid me getting into things you have corrected as opposed to beating you up—you get my point.

Mr. VLADECK. Yes.

Mr. HORN. If the gentleman would cite the reference?

Mr. SESSIONS. We were on page 4, Mr. Chairman, the GAO report, May 1997 Medicare Transaction System, MTS. Sir, I am on the second paragraph, the last——

Mr. HORN. Begins: "The risks associated . . ."

Mr. SESSIONS. It does. The sentence that I am after: "Further, HCFA is relying on . . ." And if you like, I will provide that in writing.

Mr. HORN. Without objection, that exchange of letters will go into the record at this point.

Mr. SESSIONS. Thank you, Mr. Chairman.

Mr. VLADECK. We will do that.

[The information referred to follows:]

Hearing before the
Committee on Government Reform and Oversight
on "Status of the Medicare Transaction System"
May 16, 1997

MATERIALS FOR THE RECORD

Attached are answers to questions to Bruce Vladeck, Administrator, Health Care Financing Administration:

Mr. Sessions asked a question related to the following paragraph from a GAO report:

> "Further, HCFA is relying on its Medicare systems contractors to assess, plan, and implement essential changes for the year 2000 issue, but it is not closely monitoring these critical activities or receiving certifications or assurances from contractors that the problems will be corrected." (P.64 of transcript)

HCFA's Administrator disagreed with GAO's assessment, and Mr. Sessions asked for HCFA's latest analysis that could be provided to GAO if they were doing their study today, addressing the smaller issues and how HCFA would have responded.

Answer:

In order to monitor Medicare contractors and assess their progress with Year 2000 changes, we have:

- established a Regional Office workgroup to assure that changes are being made that will make the contractor systems Year 2000 compliant by the end of 1998;
- contacted all the contractors asking them for their project plans for making their systems Year 2000 compliant, and we are analyzing their initial responses;
- established a contractor survey report to track contractors' progress against their project plans on a quarterly basis.
- contracting for an Independent Verification and Validation (IV&V) contractor to review contractor test plans, test data and test results as well as assure that all data exchanges have been identified and tested.

The status reports are reviewed by the Regional Office workgroup representatives as well as the Central Office millennium team against the project plans submitted by the contractors to determine that they are progressing according to schedule. As some of these systems are modified, we will be prescribing, and in some instances conducting, validation tests to be sure that compliance was achieved. A brief list of the major accomplishments of the Year 2000 Project for both the internal and external HCFA systems follows:

Year 2000 Accomplishments:

-Began investigating the Year 2000 problem in HCFA (November, 1994)

-Set up a Year 2000 planning team among HCFA components (April, 1995).

-Held Year 2000 awareness briefings at all levels throughout HCFA (1995-Present).

-Completed survey of HCFA's major internal and contractor systems to develop an initial scope and cost estimate for Year 2000 changes (April, 1996)

-Set up a full-time, Year 2000 project staff for project management and coordination.

-Conducted risk analysis on HCFA's internal systems identified by the initial scope survey and prioritized and scheduled conversion for each system based on that analysis.

-Provided funding for contractor systems (Part A and B) and the Common Working File (CWF) system for Year 2000 changes.

-Received conversion plans from all shared systems (May 1997) and survey responses from all carriers and intermediaries. Based on an analysis of this information, milestones will be incorporated into the HCFA-wide project plan.

-Established a Regional Office workgroup and a quarterly reporting system to monitor Medicare contractor plans and progress on making Year 2000 changes.

-Established a Technical User Group (May 1997) to work with HCFA's external partners, including: carriers, intermediaries, standard system maintainers, Peer Review Organizations, State agencies and HMOs.

-Identifying all data exchanges between systems down to the file level (by June 1998).

-Developed a tracking system and database to monitor the progress of systems' conversion.

-Established a test environment at HCFA's data center to allow the systems' dates to be changed to Year 2000 and beyond (September 1997).

-Contracting for and working with an Independent Validation and Verification and testing contractor to assure the quality of the Year 2000 changes and assist with testing (for internal and external systems).

Mr. Horn (p.78) asked for some assurance -- "let's say how many millions of lines of code have been gone over, or has anything happened to your in-house system that would give us sort of a

good feeling...that something has happened in this?"

Answer:

Of the twenty million lines of code in our Medicare contractor standard systems that must be reviewed, the review of 8 million lines of code has been completed. Review of the remaining 12 million lines of code are in progress and needed changes are being made. All of this work is scheduled to be completed by December, 1998.

Mr. SESSIONS. One last point, if I could. Further on page 4—you probably could draw the conclusion that I read to page 4—there is, two paragraphs down: "MTS is not being adequately managed as an investment." And then last, further down: "Also since 1992, when the first analysis was completed, the total cost of the project has increased from $151 million to about $1 billion."

Can you please simply give me some comment on that, those two thought-processes?

Mr. VLADECK. Yes, sir. If I can do the second one first?

Mr. SESSIONS. Please.

Mr. VLADECK. I think if you look at the sentence immediately following the $151 to $1 billion, you will see the inference which we would certainly strongly support that the difference between the $151 million and the $1 billion is partially an apples and oranges problem. That is to say, the $151 million dollars estimate in 1992 was not inclusive of the actual physical facilities for the operation of MTS nor for the transition of contractors and the costs associated with closeout costs and other Government obligations that are associated with such transitions. Those were clearly not part of the $151 million; they are part of the $1 billion.

Having said that, I think it is also true and fair to say that our conception of what the system is in 1997 is very different from what it was in 1992. But I would also say that one of the things for which we specifically contracted was for a design and specification of the system, and that was produced for us by GTE in late 1994 or early 1995. On the basis of that, we have been able to make much more informed estimates.

On the issue of managing as an investment, I think the detail of that that is described elsewhere in the report by GAO really has to do with sort of a systematic evaluation of risk and mitigation strategies, and, consistent with this notion of investment strategies, some of the legislation that Congress has enacted in the last couple years such as the Clinger-Cohen Act, the Office of Budget has established a set of eight principles by which to lay out the criteria by which to establish whether a project meets appropriate investment management criteria.

And we have, I believe in our letter to Mr. Shays, included a copy of a letter to the Office of Management and Budget, in which we describe the extent to which we believe we are or are not meeting those eight principles. We have a way to go on some of the components of it, but we are clearly moving toward a State, once we have the revised project plan, when we will be able to meet all eight of those criteria. Clearly, that is something we need to do that we have not adequately done in the past, but we will be doing over the next several months.

Mr. SESSIONS. Mr. Chairman, I have exceeded my time. Thank you.

Mr. HORN. If you have a followup question or anything, feel free to ask it?

Mr. SESSIONS. Well, the followup question I guess I would really have is: It seems like what you are attempting to describe to me is that the original configuration, perhaps the original contract, the architecture, the design and plan of that has changed multiple

times, and now you are attempting to retrofit, and that that is why you are having trouble?

Mr. VLADECK. No. I think it is fair to say two things. We largely acknowledge when we let the contract that well, we could specify what we wanted the final system to do. We didn't know what it would look like in terms of how many hardware sites we would need, how many, what kind of telecommunications we would need, how much software would need to be written, and so forth, and a large part of what we have paid GTE for is that design of a system, which we didn't have when we started. We specified what we wanted the system to be able to do, but we didn't know what it would look like.

The other thing that has changed, though——

Mr. SESSIONS. You did not know what you were asking for?

Mr. VLADECK. No. We knew what we were asking. We specifically communicated with GTE to design a system that would be capable of achieving certain objectives and performing certain functions. That's what the first part of the GTE contract was about.

Once we got that systems design and began to put it in place, there was one other very significant change, and that was, as a result of our experience with GTE, our advice from our independent verification and validation contractor, the advice from GAO, the advice from this subcommittee and others, were very concerned that the plan that we developed to implement this system was a so-called "big bang" plan. It relied on putting a lot of pieces together that were all new, all at the same time, and having a new system that was up and running and you would flick a switch and leave the old system and move into the new system.

Having a new system that was up and running, and you would flick a switch and leave the old system moving into the new system, and we were advised by lots of folks that that was not a prudent strategy, that that increased the risk of total failure, and it increased the risk of spending too much money. So beginning last summer, we modified the strategy to, in the terms the computer folks used, reduce concurrency and make the implementation plan more chunky, and we are still very much in the process of seeing if we can continue to break it down into even smaller pieces, which are less dependent on one another, and it is, in the political sense, instead of going for the whole thing at once, we are in a much more incremental strategy at the moment.

Mr. SESSIONS. And now someone is finding fault with that.

Mr. VLADECK. If I understand what GAO is saying, they are saying we are not yet being incremental enough and saying we need to look at some even more incrementalist options.

Mr. SESSIONS. So too big a bite, you can't swallow what you chewed; is that the philosophy?

Mr. VLADECK. I think that is a fair way to characterize it; yes, sir.

Mr. SESSIONS. Thank you.

Mr. HORN. I thank the gentleman for that very penetrating series of questions.

Now let me just ask a few closing questions. The rest we will have staff exchange with you. You are still under oath when you answer those.

Let me start out with, to what extent is the Health Care Financing Administration still dependent on the computer systems of the Social Security Administration for any of its eligibility determinations or anything else that it relates to that?

Mr. VLADECK. The Social Security Administration still has responsibility for actually doing the initial eligibility determination, and enrollment of Medicare beneficiaries, and changes in enrollment status, such as changes in marital status or changes in—or deaths of a beneficiary are still generally coming to the system through Social Security. We are on a dedicated line, a data-center-to-data-center, data exchange with Social Security, and we do maintain beneficiary records for the Medicare program. But much of the input into that record system, the great bulk of the input, comes on a tape-to-tape basis, essentially from Social Security, and comes through the Social Security computer systems.

Mr. HORN. So, conceivably, if they solve the Y2K or year 2000 problem, you wouldn't be at fault on failing to have the proper eligibility data because presumably they have been working on this problem since 1989 and are ahead of every other agency on that.

Mr. VLADECK. Well, we do maintain our own file with our own software associated with the file. It's not just a copy of theirs, and so we have our own obligation for our own beneficiary records to make sure that all potential year 2000 risks have been addressed. We can't pawn it off on them.

Mr. HORN. Now on that year 2000 risk, if I read in the GAO report, on page 27, on March 26, 1997, the Health Care Financing Administration asked its Medicare contractors to provide an inventory of the Medicare applications affected by the year 2000 change and their schedules for converting, replacing or eliminating these systems. Then it says, a little further down, on April 22, 1997, at the conclusion of our review, the Health Care Financing Administration provided us with information regarding a technical work group, which is to identify and resolve any year 2000 technical issues. However, this work group, which was established on January 10, 1997, had not yet discussed or resolved any technical issues.

Now, do you think our pace is appropriate to get this—in other words, I am wondering how seriously do you take this problem?

Mr. VLADECK. Again, I think there is some confusion in this report, and I would have to double-check. There are two processes going on. One is the year 2000 work that our contractors are doing and have been doing for more than the past year. The second is our in-house year 2000 work, and which I believe that the technical work group referred to in the last paragraph of this session largely refers to our in-house systems, not to the basic Medicare claims processing systems. That is the work group that was established on January 10. It replaced several earlier staff efforts that had been going on since 1996 on the year 2000 issues and has taken responsibility for the in-house software.

But the contractor software, we have been working with the contractors since 1996 to do year 2000 in the claims processing software, and we are monitoring that on a quarterly basis. The March 26 request is a routine quarterly reporting request.

The independent validation question, we will ourselves be doing validations. We have not identified a third-party contractor to do

the work of our Medicare contractors, but on the basis of the GAO's recommendation, that is something we ought to look at.

Mr. HORN. So presumably, your contractors, if they do not meet that Y2K criteria, would not have earned their payment; is that the way the contract is written?

Mr. VLADECK. We would be in a position to withhold funding from them, yes.

Mr. HORN. You could withhold funding.

Mr. VLADECK. On an issue of this sort, again, we will be testing at the very end of 1998 and 1999, in early 1999, whether they have achieved those changes, and I would suggest that if there are contractors, by which—by the first quarter of 1999 or the year 2000 are not compliant, we would probably seek to move the work to compliant contractors rather than hold our breath and hope they would fix it in a remaining period of time.

Mr. HORN. So this committee I cited is really more interested in the in-house conversion.

Mr. VLADECK. That is correct.

Mr. HORN. To what extent—let's say, how many lines of—millions of lines of code has been gone over, or has anything happened on your in-house system that would give us sort of a good feeling when we leave for lunch that something has happened in this?

Mr. VLADECK. I regret, I actually saw last week the latest report of our task force, which had the number, both the total number of lines of code that had been identified as requiring modification and the lines that had been rewritten to date, and I don't remember those numbers. I would be happy to supply them to you as part of the supplemental material.

Mr. HORN. It will be at this point in the record, not wherever that other thing is.

Mr. VLADECK. Wherever it is, we will have it for you.

[The information referred to follows:]

DEPARTMENT OF HEALTH & HUMAN SERVICES

Health Care Financing Administration

The Administrator
Washington, D.C. 20201

AUG 22 1997

Mr. R. Jared Carpenter
House Subcommittee on Human Resources Clerk
Washington, D.C. 20510

Dear Mr. Carpenter:

At the May 16, 1997, hearing on Status of the Medicare Transaction System (MTS), at which I testified on behalf of the Health Care Financing Administration (HCFA), you asked for further information on specific subjects. My staff and I obtained the information you requested, and provide the following responses to your questions:

Q: What is the total number of lines of source code that has been identified as requiring modification?

A: Twenty million lines of code were identified by HCFA as requiring modification for the Medicare standard systems.

Q: What is the total number of lines that has been re-written to date by HCFA's Medicare contractors for the year 2000 project?

A: Approximately 8 million lines of codes have already been re-written and the additional 12 million lines are expected to be completed by December 1998. The cost of rewriting a single line of code has been estimated to be $1.10, and the funds for this project have been allocated in the fiscal year 96-98 budgets.

We believe the development of a single, integrated system for tracking Medicare and Medicaid claims is critical to the preservation of these programs. Similarly, the timely transition of computer programming to the year 2000 source code is an important step toward our ability to meet the challenges of the next century. We acknowledge and appreciate the interest of Committee Members in HCFA's efforts in MTS and related projects.

I trust these responses adequately address your questions. Please do not hesitate to call me if you have further questions or concerns.

Sincerely,

Bruce C. Vladeck
Administrator

Mr. HORN. So I am wondering, is there anything else that should be done by your agency, that you feel should be done as the Chief Administrator, to make sure that both the in-house and the contractor Y2K approaches are moving along in a timely way?

One of our real concerns is that a lot of people aren't going to discover that the efforts they have made are going nowhere until late 1998, maybe late 1999, and the resources cost of hiring the people that know what they are doing are going to be sky high because everybody will suddenly have awakened, and then they will have a problem.

So we are trying to get the Federal executive branch and the Office of Budget and Management to take the lead in this on behalf of the President, get them moving in some steady way so we don't have them yelling and screaming about Congress, you have to appropriate something here. The Director of the Budget, Dr. Raines, and I agree, this ought to be reprogrammed money. We shouldn't be wasting the year up here going through an authorization and an appropriations process. We should be doing the end of the year money, which happens in every agency, and if they don't, there is something wrong with the administration, and put that to work on where the critical problems are.

This is a critical problem, and I must say, my other 434 colleagues in the House will be delighted when you get these systems because we would probably have to double our field in the district offices just to handle the complaints, and yours is obviously the one our citizens care about the most.

Mr. VLADECK. Let me just say that we, in fact, began by reprogramming fiscal 1996 money to support the initiation of this work with our contractors. We have 1997 money, but I would also be unable to resist, Mr. Chairman, the plug that in the President's 1998 budget request for HCFA, we have identified $10 million for the in-house data systems for year 2000 reprogramming work that we think is not otherwise available within the budget request, and since you have given me the opportunity, I feel I should note that for the record.

Mr. HORN. And since I am going to give you a further opportunity, since you are under oath, and it is a question you now have to respond to—you couldn't before the budget is released—what did you ask for?

Mr. VLADECK. We got what we asked for.

Mr. HORN. You asked for $10 million, and you got it?

Mr. VLADECK. That's correct.

Mr. HORN. From a recommendation of the President?

Mr. VLADECK. That is correct.

Mr. HORN. So that is part of the $2.3 billion, which is, frankly, underfunded, probably, because they don't have the analysis. It's like this whole discussion. The planning work hasn't been done, the analysis hasn't been done, it is just rhetoric flying around, and until it gets done, we won't know.

I suspect it is going to be closer to $10 billion now. Cortner and Associates said it would be a $30 billion problem. I always thought that was a little high. But I think as we get into it, the Pentagon alone might have $5 billion of that, and there is certainly $1 billion of the current $2.3, and they testified before us that they hadn't

even gotten into the analysis yet where you would look at the number of the lines of code that you have to deal with. So unless the gentleman from Texas has any further questions, I will excuse you.

Mr. SESSIONS. Sir, just a statement, and I do want to end it because I want to go to lunch, also. I think that what we are really trying to say is that you are the person with your hand on the wheel. You have come to us today and said you have confidence in what is going on. That is slightly different than what we may be looking at and observing in this GAO report that you think you have addressed some of those things more near term. We are deeply interested in your success, and if we have communicated that to you today, that is important.

Likewise, I think what the chairman has said, maybe not point blank, is if in your evaluation you run into trouble, please do not wait for us to call you. We would like for you to notify this body. Our chairman is among the best in Congress, and we can deal with problems if you spot them to us early. It becomes more problematic the longer you wait.

Mr. VLADECK. I hear that loud and clear, and I appreciate it.

Mr. SESSIONS. Thank you, sir.

Mr. VLADECK. I appreciate it very much.

Mr. HORN. Well, what Mr. Sessions has said is very well said, and I thank him for his generosity. In a previous incarnation, 32 years ago, when I was the assistant to the Republican Whip of the Senate, Senator Kuchel of California, I happened to be on the Medicare drafting team and worked closely with Wilbur Cohen, who was the inspiration for all this. And you have one of the toughest jobs in Government, but one of the most important, because what Medicare has done is make this a far different Nation than it would have been without Medicare. Just think of what we could not have done and accomplished without Medicare basically.

Mr. VLADECK. We have a strong sense of responsibility about that, and we really do appreciate the involvement of the subcommittee in helping us through some of these things. We will provide you with the supplementary material you have requested, and we will be regularly in touch about the MTS issue in general and about the Y2K issue specifically, and we appreciate it very much.

Mr. HORN. Well, we thank you very much for coming and appreciate what you and your staff have done in the presentation.

We will now go to the third panel. Mr. Zaks and Mr. Burton.

Gentlemen, if you will raise your right hands?

[Witnesses sworn.]

Mr. HORN. The clerk will note both witnesses have affirmed, and on our agenda here, first, you, Mr. Zaks.

First, Irving Zaks, vice president and general manager of the information systems division of GTE. I come from an area where GTE served, and we are very glad to have you here.

STATEMENTS OF IRVING ZAKS, VICE PRESIDENT AND GENERAL MANAGER, INFORMATION SYSTEMS DIVISION, GTE; AND BRUCE BURTON, VICE PRESIDENT, INTERMETRICS SYSTEMS SERVICES CORP.

Mr. ZAKS. Thank you, Mr. Chairman. I have a statement, which, with your permission, I will submit in its entirety for the record.

Mr. HORN. Right. At this point it is inserted in full, and if you would like to summarize your statement, we will appreciate that.

Mr. ZAKS. Thank you.

Mr. Chairman and other members of the subcommittees, thank you for inviting me to appear before you today. As you know, GTE is a system design contractor to the Health Care Financing Administration on the MTS program. In my position as vice president, I am responsible for all Medicare Transaction System program activities at GTE. We are pleased and proud to be part of the MTS development team.

I believe you invited me here today because you wish to realistically assess the MTS program's present status and learn from our experiences to date. So I will begin by saying that, yes, the MTS program has had many significant challenges, and GTE has not been perfect in helping HCFA overcome some of them. There are several factors which account for the present condition of the program. Those factors must be considered as you review the program's progress and influence its future.

First, consider that MTS is one of the most complex system development programs ever undertaken by Government or the private sector. The 14 Part A and Part B claims processing systems being replaced were conceived and developed when the science of computer programming was in its infancy. The systems were developed independently from one another. They operate on different hardware platforms, and they are poorly documented.

Second, our inability to accurately predict the complexity of those systems during our proposal development activities for this program led us to underestimate the level of effort and time required to develop the new system. As our understanding of the requirements generation activity matured, the time and cost required to complete it has increased, and the resulting schedule has extended.

Third, as you are aware, interpretations of the rules that govern Medicare claims vary from State to State. Establishing a set of common interpretations that apply nationwide and then identifying exceptions to those rules, which the new MTS system must also accommodate, has been and continues to be a major challenge. This is probably the most significant cost-growth factor, solidifying a common set of interpretations as a baseline requirement set from which to proceed with the design. This has been a much slower process than anticipated.

These three factors are the primary causes for the cost growth and schedule slippage that other witnesses have described today. Despite these challenges, we have made much progress in conceiving, designing, planning and implementing major portions of the system. The first component, release 1, is scheduled for delivery in June 1998. Release 1 will be a significant achievement. Not only will it enable HCFA to improve service to Medicare beneficiaries, release 1 will incorporate security features to protect the privacy of beneficiary records, and it will provide a platform upon which HCFA can build future functionality.

It is true that everyone involved in the MTS program wishes that more progress had been made to this point, but in my opinion, the investment made to date, the work and the accomplishments which

are behind us on the MTS program, are well worth the savings that will be realized when the system is completed.

As industry and Government's understanding and the use of technology improves, we will envision better ways of delivering service to the citizens of this country. There will be more instances like this one where we will be forced to pause, rethink and reconceive projects based on what we discover in the systems being replaced. We, industry and Government, will get better at it every time, but there are certain learning experiences that cannot be avoided. I truly believe that the requirements generation process of this program has been one of them.

Mr. Chairman and members of the committee, thank you for your time and consideration. I will be happy to answer any questions you may have at this time.

[The prepared statement of Mr. Zaks follows:]

Good morning, Mr. Chairmen and members of the Subcommittees. I am Irving Zaks, and in my position as vice president and general manager of the Information Systems Division, I am responsible for all Medicare Transaction System (MTS) related activities at GTE. Thank you for inviting me to appear before you today regarding the status of the Medicare Transaction System program. As you know, GTE is the system-design contractor to the Department of Health and Human Services' Health Care Financing Administration on this program. GTE is pleased to be part of the MTS development team.

The Medicare Transaction System is an essential component of the Health Care Financing Administration's objective to improve service and responsiveness to Medicare users, beneficiaries, and internal customers to significantly reduce Medicare fraud, waste, and abuse. Without MTS, it will be a great challenge for HCFA to keep pace with the growing demands of an aging population, future legislative changes, and the accompanying opportunities to defraud the government inherent in the present payment system. These ongoing vulnerabilities have been well chronicled by Congress, the General Accounting Office, the media, and others.

The MTS program has had many significant challenges, and GTE has not been perfect in helping HCFA overcome some of them. It troubles me to acknowledge that so directly, but I believe you asked me here today because you wish to realistically assess the program's present status and learn from our experiences to date. As an engineer and businessman, I value the opportunity to review our approach and share our lessons learned with all parties of interest.

Before I continue I feel compelled to caution against the inclination to categorize the MTS with other large-scale federal system-development programs that have encountered unexpected difficulties and have been unable to make substantive progress towards their program goals. That is simply not the case with the MTS. In some ways, MTS had similar problems, but I believe that this program has overcome them. All large-system developments of this complexity, whether managed by the government or developed in the private community, share similar challenges. Our commercial counterparts have had their share of disappointments too. However, those developments do not make the front page of The Washington Post. The unique characteristics of large-scale systems like MTS demand that they be examined individually and evaluated independently of one another.

That said, there are three issues I will address today to assist you in assessing the status of the MTS program: first, the complexity of the existing payment systems and the implications of that complexity on any effort to consolidate, streamline and modernize HCFA's Medicare claims processing systems; second, the cost growth that we have encountered, primarily due to the existing system's complexity; and last, our view of the present status of MTS.

Complexity

MTS is one of the most complex system-development projects ever undertaken, by a Federal agency or anyone else. Briefly, I'll explain why.

At the time of contract award, MTS consisted of a total of 14 claims-processing systems, including six (6) Part A claims systems and eight (8) Part B claims systems. Those systems themselves were consolidations of as many as seventy (70) other systems that had existed previously, some dating back to the early 1960s, which HCFA wisely sifted to the current level over time.

These 14 Part A and Part B systems were used to process Medicare claims by 79 private contractors at 62 processing centers across the country. Overlaying those programs is another system called the Common Working File (CWF) which provides a modest level of cross-checking and coordination of claims and data among the 14 major systems. The CWF operates at nine processing centers around the country.

Each of the 14 Part A and Part B systems to be replaced is unique, complicated, and in some cases proprietary. The systems are the product of years of development by dozens, perhaps hundreds, of software developers and engineers, and each was created independently of the other systems. None of them was very well documented while being developed and modified over the years.

To be clear, when I say "system," what I mean is the software code written for each Part A and Part B "system." Most of these programs are written in an obsolete programming language called COBOL which instructs the computer on how to receive, manipulate, process, communicate and store all of the data that comprises each claim filed. Because of the way COBOL works, instructions for processing a claim – the real mechanics that probably do not change much over time – often are embedded in the same string of code with data that does change. This is important because, as the Medicare program has changed over time and the processing systems have been modified to accommodate those changes, much of this code was left in place, changed or deactivated, instead of being deleted from the system altogether. The result is sometimes referred to as "spaghetti code," because of the way it is intertwined. In addition, these systems were not written with the expectation that they would still be operating 30 years later and were not designed to easily accommodate the number of changes made.

Industry now recognizes that this is an unacceptable method to write code, but it was a commonly accepted practice when many of these systems were developed. And even though there are industry protocols and standards, not every system is structured to process the same function the same way. Not all of them operate on the same hardware, either, so each system contains additional variables related to the specific machines the software operates on. In addition, most of these systems are comprised of more than a million lines of computer code each. This further complicates an already complex requirements environment.

Another complicating factor, and one which MTS must accommodate, is that the claims rules vary from state to state, and each legacy system complies with different sets of claims rules. For example, a doctor in Connecticut, in complete compliance with Medicare rules, may treat an asthma patient differently than a doctor in California. The system responsible for processing

claims in Connecticut operates with one set of claims rules with which its customers must comply, while the system in California and many other states may operate under a different set of compliance rules, frequently based on local exceptions to the interpretation of the law. These elements are the "system requirements" that have been so difficult to document. MTS must also be able to assimilate all of the data previously collected, analyze it, store it for future reference and be able to accommodate future changes to these rules as applicable.

Developing a "new system" that incorporates many of the requirements of the "old system" is extremely difficult without a comprehensive set of documentation to serve as a convenient starting point. Much of the augmented requirements analysis and integration schedule slippage was expended to determine the process that should be undertaken to establish these requirements. This process has been solidified through trial and error, and is presently being used successfully on the program.

To summarize, the MTS team did not begin with a solid foundation of information. The level of complexity and sheer magnitude of system requirements to be mapped, the lack of documentation, and the need to accommodate the unique claims rules that each system was designed to handle caused delays in the program schedule. The majority of this work is behind us, and the new MTS will bring with it the flexibility required in order to be the responsive Medicare payment system the country needs. Which leads me to the second issue: cost growth.

Cost Growth

Prior to contract award and throughout the preparation of our proposal to HCFA we diligently attempted to gather as much information as possible in order to bid the MTS program. I am certain that the other competitors were just as busy and just as unsuccessful in establishing a realistic requirements baseline to bid. Despite these efforts I believe that the field of competitors did not fully appreciate the complexity of this program.

This was exacerbated by the need to develop a methodical process that would quicken the transition from a conglomeration of contractor payment systems (legacy systems) to the MTS system. Few contractors or agencies have undertaken a project of this magnitude without a mature process, developed and tested over time. The unique characteristics of this large-scale system virtually preclude the use of models from other programs. Therefore, GTE underestimated the resources required to complete the requirements-development component of the MTS Program. This was not due to issues of process maturity; certainly we have successfully performed on other programs with similar issues. It was due to the unknowns associated with the complex system requirements environment.

I do not mean to imply that the program strategy was in any way flawed. Under the circumstances, HCFA attempted to construct an adequate Request for Proposal that permitted a fair competition. The program challenge was great, the need for a new payment system was even greater. A reliable methodology to accomplish this important system requirements phase of the

program's objectives was unavailable, simply because there was no prior need to model such a process.

These factors – inability to predict the complexity of the assignment; the need to develop a new process to make the transition between the 14 existing systems and the new system; the challenges in reliably documenting the variations in claims rules; and functions added to the immediate scope of work – resulted in the program cost growth.

Present Status

As you are aware, GTE's efforts were redirected through the stop-work order that HCFA issued to GTE on April 4, 1997. For a period of 90 days we have been directed to work specifically on Release One development. At this time, we are making great progress in developing the system. The completion of Release One will complete the Managed Care Payments component of the MTS system. Release One will also provide the security features that will protect beneficiaries' privacy, in terms of both financial and medical data. These features have been designed and tested and will be operational in June 1998. In addition, Release One will provide the systems infrastructure upon which future releases and functionality will be built.

Briefly, in spite of the challenges encountered, we have accomplished much. Among the program milestones achieved are the following:

- The overall system infrastructure/architecture has been developed and is being implemented. This includes identification of the specific hardware and operating systems components, telecommunications networks, storage requirements and technologies and the physical attributes of the three major processing centers where MTS will ultimately operate.

- Completion of the system infrastructure – known as the System Design Alternative document – enables HCFA to proceed with the procurement for contractors to operate the three sites referenced above.

- System requirements – the payment-processing rules – for the Managed Care component have been identified and the software to support those functions is under development. This component is scheduled for delivery in June 1998.

- Prior to the stop-work order, we were developing the requirements for Release Two, and we had initiated the preparatory work for Release Three. Release Two system requirements were approximately two-thirds complete when the stop-work order was issued.

These accomplishments may appear modest; they are not. They represent significant progress toward development and delivery of the MTS system. The architecture/infrastructure component is especially critical, as it will provide a tested and verified platform or foundation upon which additional functions will be layered. Inherent in delivering that platform is the

migration and transfer of significant amounts of claims and beneficiaries data from the current system databases to the new system.

Summary

Development of the Medicare Transaction System has indeed taken longer and cost more than initially planned. Largely at fault for this condition are the very systems that the MTS will replace.

The 14 legacy Part A and Part B claims processing systems were conceived and developed when the science of computer programming was in its infancy. The systems were developed independently of one another. They operate on different hardware sets and they are poorly documented.

In addition, the claims rules the systems accommodate have changed many times and will continue to change, as permitted by law. Establishing a baseline set of rules that captures the claims filed, and then identifying exceptions to those rules that also must be accommodated, has been a major challenge. Cost growth and schedule slippage are primarily the product of these factors.

Nonetheless, much progress has been made in conceiving, designing, planning and implementing major portions of the system. The first component, Release One, is scheduled for delivery in June 1998. Along with the infrastructure (hardware sets, processing centers, networks and databases) based on the architecture we developed to support future releases and functions, Release One will be a significant achievement.

In my opinion, the investment made to date in MTS is well worth the savings that will be realized once the system is completed. I believe everyone who has been involved in the program wishes that more progress had been made to this point. However, I also believe that regardless of when this project had been undertaken, by whomever else might have been chosen, very similar difficulties would have developed.

As industry and government's understanding and use of technology enables us to envision better ways of delivering service to the citizens of this country, we will be forced to back-up, re-think and re-conceive projects based on what we find in the legacy systems that they are to replace. We – industry and government – will get better at it every time, but there are certain learning experiences that cannot be avoided, and I truly believe this is one of them.

Thank you for time and consideration, Mr. Chairman and members of the committee. I will be happy to answer any questions you may have at this time.

Mr. HORN. Thank you very much for your statement, and we now turn to Dr. Bruce Burton, the vice president of the Intermetrics System Services Corp. Welcome.

Mr. BURTON. Thank you. Mr. Chairman and members of the subcommittee, I am pleased to participate in this joint subcommittee hearing today to discuss——

Mr. HORN. You might want to get that microphone a little closer to you and bring it down a little. Those are awful microphones, and neither of your companies had anything to do with them, I am sure.

Mr. BURTON. I can assure you.

We are submitting the statement summarizing our role as the independent verification and validation contractor in support of the Health Care Financing Administration's development of the MTS. I am also prepared to answer any questions from the background regarding our efforts.

In order to provide you some background on Intermetrics, we are a 28-year-old software company with over 500 software systems professional, with approximately $55 million in annual revenues. We are headquartered in Burlington, MA, and we have 11 operating offices throughout the United States located near major customers, including approximately 150 personnel in the Washington metropolitan area.

For over 25 years, Intermetrics has provided IV&V services to major customers, and in addition to HCFA, our current customers for IV&V services include NASA for IV&V of the space shuttle, space station, critical ground systems and robotics spacecraft; Immigration and Naturalization Service; the U.S. Army; and more recently, the U.S. Postal Service.

In addition, Intermetrics provides year 2000 verification and validation support in the financial services arena. Our work on the MTS IV&V contract emphasizes MTS software life cycle product evaluation and MTS technical support. The IV&V contract deliverables include a monthly progress report of the IV&V effort, the MTS contract reports to HCFA through the HCFA IV&V project officer who is responsible as the technical monitor of the contract. To facilitate communication, senior management from Intermetrics frequently meets with senior management at HCFA.

Going on to our view of the MTS project. Intermetrics began its IV&V of the MTS contract approximately 3 months after contract award to the MTS design contractor. One of the IV&V's early findings was the risk inherent in the design contractor's decision to abandon the analysis approach that was described in the original proposal and to replace that analysis approach with processes that eventually resulted in inefficient production of system requirements, and these requirements had been of an uneven quality.

After a set of top-level system requirements were developed, IV&V advised the HCFA MTS management staff to move toward a multiple release strategy and to prioritize the releases. This was adopted by HCFA, and it's reflected in the design contractor's contract in mid-1996. IV&V recommended that HCFA focus the design contractor on the early MTS releases, institute an MTS program management matrix program, and initiate a contingency planning process. HCFA, in collaboration with the design contractor, decided

to move ahead with the parallel release strategy in concert with adopting IV&V's risk management techniques of the metrics-based oversight program and contingency planning.

Based on the design contractor's schedule and cost performances identified by the metrics program, HCFA issued a 90-day stop-work order to the design contractor on April 4. During this 90-day period, HCFA with IV&V input, as well as others, will reassess the design contractor's future role and evaluate MTS development alternatives and select a preferred solution. IV&V agrees with HCFA's actions.

In conclusion, the MTS project is complex, and it will require substantial management attention always to keep it on track. While IV&V acknowledges that the MTS will not achieve its initial schedule or cost objectives, we believe that HCFA is exercising good management judgment in focusing the design contractor on the first MTS release and reviewing their alternative MTS development options.

Finally, IV&V is optimistic. We believe that the original MTS goals can be successfully achieved through HCFA evaluation and selection of alternatives during this 90-day period. This implementation of a revised plan will most likely be on a different schedule and cost, but we also believe that the benefit of a good return on this investment can be achieved.

Mr. HORN. Thank you very much.

[The prepared statement of Mr. Burton follows:]

PREPARED TESTIMONY BY INTERMETRICS, INC.

Mr. Chairman and Members of the Subcommittee:

We are pleased to participate in this joint subcommittee hearing today to discuss the status of the Medicare Transaction System (MTS) project. We are submitting this statement summarizing our role as the Independent Verification & Validation contractor (IV&V) in support of the Health Care Financing Administration's (HCFA) development of the MTS. We are also prepared to answer any questions from the Committee regarding our efforts.

Background

In order to provide you some background on Intermetrics, we are a 28 year old software Company with over 500 software systems professionals, and approximately $55 million in annual revenues. We are headquartered in Burlington, Massachusetts with 11 operating offices throughout the U.S. located near major customers, including approximately 150 personnel in the Washington, D. C./ Virginia/Maryland area.

We provide software development life-cycle services and software assurance, and verification & validation services to a wide range of federal government and commercial customers. Our software assurance IV&V and Test & Evaluation (T&E) service is a major business area for the company and, in fact, represents approximately 40% of our revenue base. For over 25 years Intermetrics has provided IV&V services to major customers in the DoD, other federal government agencies and Fortune 100 commercial companies. These IV&V contracts have been performed on a wide range of major critical systems, including new systems development and upgrades to legacy systems.

Our current customers for IV&V services include: NASA -associated with IV&V for the Space Shuttle, Space Station, Ground Systems and Robotic Vehicles - all mission safety critical systems; the Immigration and Naturalization Service (INS) - performing a variety of quality and quality assurance roles for the upgrade of their legacy systems and implementation of new field systems; the U.S. Army - Communications and Electronics Command (CECOM) performing T&E for new and upgraded communication and electronic systems; U.S. Postal Service - recently selected as the IV&V and T&E contractor for the upgrade and modernization of postal systems; Prudential Insurance Company of America - supporting the implementation of a software quality program and in support of quality and test and verification of the Year 2000 Systems upgrade; J.P. Morgan - providing quality test and verification for the upgrade of legacy systems for the Year 2000.

These projects include multi-year contracts (in some cases for as long as a 10 year period) and range in size from approximately seven people to over 60 people. In summary, Intermetrics has substantial experience and qualifications in providing IV&V and T&E for mission critical systems that require high reliability and must work correctly.

The role of an IV&V contractor varies with each customer and each system, and generally is customized to meet the specific needs and budgetary constraints of a customer. IV&V is an

engineering process to oversee the work performed by the development contractor generally consists of an independent appraisal of products produced during the development cycle including an assessment of completeness, accuracy and traceability throughout the development process. A comprehensive IV&V effort would include an independent assessment of the requirements document, the design specifications, the software source code, the test procedures and activities (including in some cases an independent test effort), system integration, and verification and validation. The goal of an IV&V effort is typically to provide additional assurance to the customer that the system being built is in accordance with their requirements and to make every effort to reduce risk by identifying and detecting potential errors in the system as early as possible.

Intermetrics' Role on the MTS for HCFA

In 1991 the Health Care Financing Administration (HCFA) began developing a Request for Proposal (RFP) for a new computer system to replace 14 independent fee-for-service (FFS) Medicare claims processing systems, the Common Working File (CWF) System which provides centralized benefit management for the Medicare Program, and the data centers where these systems run. The new system was named the Medicare Transaction System (MTS) and was envisioned to be a centralized, automated environment supporting HCFA and their claim processing contractors in the administration of the FFS benefit for all Medicare beneficiaries and health care providers in the nation. When complete, MTS will be a very complex environment of software, hardware, telecommunication networks with tens of thousands of on-line users. The MTS RFP was issued in September 1992. HCFA awarded the six year (plus one option year) contract to the GTE Government Systems Corporation (GTE) on January 1994. After a brief stop-work period ordered due to a contract award protest, GTE began working on the contract in March 1994.

HCFA also issued an RFP for an Independent Verification and Validation (IV&V) contract which would provide services to HCFA to monitor the design, development, validation, and implementation of MTS. The RFP was issued in November 1992 and a contract was awarded to Intermetrics, Inc. in April 1994, approximately three months after GTE came on contract. This sequence of events was somewhat different than for other IV&V contracts. In many system development projects, the IV&V role starts prior to award of the design contract. In this manner, the IV&V contractor can provide an independent assessment of the selection process and can be in place to review the start-up activities and proposed plans of the design contractor.

The IV&V contract was for an initial period of five years with 2 one year option periods with a total potential value of 4.1 million dollars over the seven years. Intermetrics has staffed the MTS contract with an average of seven personnel over the past three years. The initial scope and statement of work of the contract emphasized MTS software life-cycle product evaluation and MTS technical support. The IV&V contract deliverables include a monthly progress report of the IV&V effort. The MTS contract reports to HCFA through the HCFA IV&V Project Officer, responsible as the technical monitor of the contract. To facilitate communication, senior management from Intermetrics meets with senior management at HCFA. IV&V also regularly meets with the Program Manager of the MTS Initiative Program, and the Director, Bureau of Program Operations.

MTS Project

The MTS project involves the design, development, and implementation of a single integrated information system to support the administration of the Medicare Program for HCFA. The system will process fee-for-service claims and make Managed Care capitation payments for approximately 37 million Medicare beneficiaries. There are over 70 Medicare claim processing contractors using one of six claim processing systems, executing at approximately 60 computer centers across the nation. MTS will replace these software systems and relocate the processing to three MTS Operating Sites. Additionally, MTS will replace the present Managed Care systems running at the HCFA Data Center and the Common Working File (CWF) system which runs at nine regional computer centers. HCFA and the Medicare contractors will be connected to the MTS processing centers by a private telecommunication network to ensure the security of the medical information being processed. Approximately one million health care providers will be connected to the MTS centers to improve the collection and dissemination of information to these HCFA customers. The main goals of MTS project are to:

- Improve the service HCFA provides to Medicare beneficiaries and providers of health care.

- Improve the level of automated support provided to HCFA's claim processing contractors so that they can administer the Program more efficiently and effectively. This should result in a reduction of administrative expenses to the government.

- Provide a national level of beneficiary, provider, claims, medical service, and benefit payment information so that the data can be analyzed to ensure compliance with Medicare Regulations, detect fraudulent practices, and identify abusive activities. This will reduce the cost of benefit payments from the Medicare Trust Funds and general revenues.

- Provide a computing environment that will take advantage of the rapid changes in technology and can be easily and inexpensively enhanced as Congress and HCFA make changes to the Medicare Program in the future.

The MTS development effort is very similar to projects undertaken by industry and other government agencies to re-engineer legacy systems into modern information systems with more information available to the users over interactive, user friendly workstations. MTS does, however, have several aspects which have influenced its development. These include:

- The undocumented level of business requirements for the current processes that must be re-engineered and included in the new system

- The complexity, size, and rapidly changing regulatory and health care delivery environment that the system must support

- The substantial pressure for a return on investment of government funds and reduction in the cost of the Medicare Program.

The original schedule for the MTS project called for the first Medicare Claim to be processed by MTS in September 1997 and the last contractor transition to be finished in December 1999. Even though the initial date for MTS generation was missed, Intermetrics believes that the original goals for MTS and the Medicare environment can still be achieved.

IV&V's Current View of the MTS Project

Intermetrics began its IV&V of the MTS contract approximately 3 months after contract award to the MTS design contractor. Intermetrics initially supported the project with review support for early requirements deliverables and with technical support for interchange meetings with the design contractor. One of IV&V's early findings was the risk inherent in the design contractor's decision to abandon their proposed analysis approach. These processes almost immediately resulted in inefficient production of system requirements of uneven quality.

After a set of top-level system requirements were developed, IV&V advised the HCFA MTS management staff to move towards a multiple release strategy and to prioritize the releases. This was adopted by HCFA and reflected in GTE's contract in mid-1996. In order to meet MTS need dates, an aggressive approach of parallel releases was proposed by the design contractor. IV&V recommended that HCFA focus the design contractor on the early MTS releases, institute an MTS program management metrics program and initiate a contingency planning process. HCFA, in collaboration with the design contractor decided to move ahead with the parallel release strategy in concert with the IV&V risk management techniques of a metrics-based oversight program and contingency planning.

Based on the design contractors schedule and cost performance as identified by the metrics program, HCFA issued a 90-day stop work on GTE on April 04, 1997. During this 90-day period, HCFA, with IV&V input, will reassess the design contractor's future role and evaluate MTS development alternatives and select a preferred solution. IV&V concurs with HCFA's actions.

IV&V has assessed many aspects of the MTS project ranging from the technical stability and quality of the design contractor's products to MTS progress and cost compliance. While we have supported the program for just over three years, our testimony will focus on the progress over the past eighteen months. During this time, the design contractor has documented the overall MTS system requirements and developed the detailed managed care system requirements. The design contractor also defined a system design architecture capable of meeting the MTS goal for accommodating information technology changes and they developed a phased MTS implementation approach with multiple system releases to help mitigate development risk.

While the MTS project has a solid technical foundation, IV&V is concerned about the project's poor schedule performance in the past and likelihood of continued schedule problems. IV&V has

worked with MTS senior management and the design contractor to institute a rigorous metrics program to yield early insight into the future schedule problems before they lead to significant program slips.

IV&V is also concerned about the poor cost performance on the MTS project. This is primarily attributable to the MTS project's complexity. IV&V believes that the development contractor's team complexity and ad hoc processes are contributing factors to the project's cost performance difficulties. The metrics program mandated by HCFA senior management with assistance from IV&V and the design contractor provides in-depth insight into cost performance. HCFA management is working with IV&V to continue to enhance its metrics program to effectively measure MTS project performance while implementing the requirements management and change control that are vital to a controlled software development.

IV&V's Role will continue to Evolve

IV&V's role on major projects almost always evolves during project execution. IV&V on the MTS project is no exception. The early emphasis on the MTS project was on product evaluation and risk identification. The development contractor focused much of their early efforts at requirements collection and design alternative selection with the dominant engineering effort coming out of their Baltimore Technical Office. As the project progresses into software design and development, the design contractor plans to increase the involvement of their software development group in the Tampa, Florida. IV&V has responded to the increased activity in Tampa by increasing our level of oversight on the design contractor's software group. We expect this level of oversight to increase over the next year.

IV&V also expects to continue to support HCFA with independent assessment of project status and cost data. We will continue our support to HCFA in the development and evaluation of MTS program alternatives and contingency planning. By tying realistic development and maintenance costs to achievable development timeframes, IV&V can support HCFA in the selection of the optimal MTS implementation path.

Conclusions

The MTS project is complex and it will require substantial management attention to keep it on track. While IV&V acknowledges that the MTS will not achieve its initial schedule or cost objectives, we believe that HCFA is exercising good management judgment in focusing the design contractor on the first MTS release and reviewing their alternative MTS development options. Furthermore, IV&V believes that HCFA is simplifying the project transition process by consolidating processing into three standard systems.

IV&V intends to continue to act as an independent assessor and to provide HCFA with access to information on best industry practices. This information will provide HCFA senior management with the data to make effective executive decisions to ensure a successful MTS implementation.

Finally IV&V is optimistic. We believe that the original MTS goals can be successfully achieved through HCFA evaluation and selection of alternatives during this 90 day period. This implementation of a revised plan will most likely be on a different schedule and cost, but we also believe that the benefit of a good return on this investment can be achieved.

Mr. HORN. Let me begin, if I might, with questions for you, Dr. Burton. At what point did Intermetrics realize that the project may have been poorly defined, and what recommendations did you make?

Mr. BURTON. Well, we did see that early on in the first year or two of the program, that some of the infrastructure that typically is in place in programs like this was not currently available, and we initiated efforts with HCFA to start working on that infrastructure.

Mr. HORN. Let me ask you, Mr. Zaks, have you been with this project from the beginning?

Mr. ZAKS. Not from the very beginning. I came on in October 1995.

Mr. HORN. Dr. Burton, to whom were those reports given?

Mr. BURTON. Those reports were given to the technical monitor of the project.

Mr. HORN. And that was an official of the Health Care Financing Administration?

Mr. BURTON. Right. That would be the technical monitor.

Mr. HORN. Who was it at that time?

Mr. BURTON. At that time, that was Mr. Larry Pratt.

Mr. HORN. And what was your feeling; did you do these quarterly, or was there a set contractual requirement as to when you reported, or how did that work?

Mr. BURTON. We report on a monthly basis, and they were included as part of that monthly report.

Mr. HORN. What is the single most important factor, do you think, that will assure the success of the MTS project?

Mr. BURTON. I really believe that it will be in a thorough assessment of the options going forward, combined with a good set of sort of development processes that will be associated with that selected alternative.

Mr. HORN. The reverse: What is the single most significant factor that can contribute to the failure of the project?

Mr. BURTON. I think that the single issue that could most contribute to the failure of the project would be to not formally accept the requirements, the system requirements, and then baseline those and put them under some form of requirements management.

Mr. HORN. What is your evaluation of the leadership of this project over the period with which you have dealt with it?

Mr. BURTON. One, let me make a caveat here, is that as part of IV&V, it is generally our responsibility to evaluate the products that are associated with the development contractor. My own assessment of the leadership that is associated with the HCFA management on the project is that they were inexperienced, but that they understood that, and so they weren't afraid to ask for help. So they have help from IV&V, and I know they have sought help as well as they have come to grips with the complexity of the project from other sources as well.

Mr. HORN. Was Intermetrics involved in the evaluation process and the resulting decision to place a stop-work order on the GTE contract, and what recommendations did you make?

Mr. BURTON. Absolutely. We made a series of recommendations, and those were implemented in short order by HCFA.

Mr. HORN. Now, is Intermetrics also involved in the current Health Care Financing Administration re-evaluation of the GTE contract as they explore other options?

Mr. BURTON. Yes, we are.

Mr. HORN. What is your role in that?

Mr. BURTON. Right now what we have done is that we have helped HCFA come up with some of the different alternatives in going forward. Our role will include working with HCFA to select the optimal path.

Mr. HORN. In terms of Intermetrics opinion, what factors do you and your staff think contributed to the slippage in the deliverable schedule, and the cost overruns associated with GTE's work on the MTS project?

Mr. BURTON. Well, I think it was a combination of the system being more complex than people had earlier anticipated, combined with the concurrency of the work. So when you look at it, when people had multirelease strategy, where they had multiple things being done at the same time, that also is impacted by the current difficulty of getting qualified IT personnel—there is a tremendous crunch for those kinds of people—have all combined to contribute to the schedule and cost difficulties of the program.

Mr. HORN. Did you see any portions of this project, either initially, as it was designed, if there was that design, or partway through as they got to be more familiar with some of the problems that would face them, did you see any relationship to the type of material that already exists in some of the private commercial sectors, and did you feel that should have been adopted rather than maybe reinvent the wheel?

Mr. BURTON. We have, in specific instances, on an informal basis, have worked with GTE wherever we could see that perhaps something could be done with COT Software to let them know about that. I can't remember any specific instances where it was raised as a major issue, though, on the program.

Mr. HORN. Why were certain risk factors deleted from your reports to the Health Care Financing Administration before these risks had been fully addressed by the Health Care Financing Administration? Why did you delete those risk factors?

Mr. BURTON. I am actually uncertain about that.

Mr. HORN. Well, was this done at the beginning level of the report, the technical staff down below, or was it done at higher levels or what?

Mr. BURTON. OK. Let me confer here with one of my co-workers if I could?

Mr. HORN. Sure. Please do. Take your time.

Mr. BURTON. I don't know specifically which issue that you are referring to.

Mr. HORN. Let me give you one. As I understand it, in May 1995, Intermetrics identified the lack of a software development plan as a risk and later removed it from the monthly report.

Mr. BURTON. Right. I think that that was based on an examination of GTE processes and development practices, and what we were shown was a variety of document and processes that they did have. So while they did not have a single software development

plan, they did have documented practices they were using on the project.

Mr. HORN. If you could go back and do some of the things over, what would you do?

Mr. BURTON. Well, I do concur with my colleagues at the GAO, where they said that perhaps it might make sense to split the contract initially up and separate the requirements generation from the development of the system.

Mr. HORN. I don't know if you were in the room when I said earlier, we have been through the FAA experience, $4 billion down the drain, first year in Congress in 1993, and I have held hearings on some of the aspects of it. We have the $4 billion of the Internal Revenue Service down the drain, and I have asked the question, can't we learn some of the problems at the $4 million mark or the $40 million mark or the $400 million mark? Do we really have to go to $4 billion? Now, I am hoping this one doesn't get to the $4 billion point where we don't know what we are doing.

So what has Intermetrics been involved in analyzing some of the other projects, and are there any others that have had the difficulty this one has had? GAO does a fine job of telling us what the best practices are, and I have always felt, whether you are talking in science or social science, we ought to give rewards for the people who write books on failures because that is the way we advance. Yet, few people want to write books on failures, unless it is a huge financial success when you are destroying somebody or whatever; but, we can learn a lot from failure. So what has Intermetrics learned over the years in terms of your collective memory that would be helpful in this situation?

Mr. BURTON. Well, one of the things that we have learned in this kind of an effort is how important it is to be vigorous about good risk management; that is, that the systems are uniformly more complicated than we expect when we get into them. There are a million ways that things can go wrong, and being constantly vigilant about that and having good plans for dealing with those and contingencies for dealing with those just seems to be a recurring factor in different systems, in fact, most of the major system development efforts that we see. There is not anything that is uncommon in the work we see either on the Government side or, in fact, on the commercial side. Many of the same difficulties we see, we see in commercial companies as well.

Mr. HORN. Have you been involved with either the FAA or the IRS contract in anyway?

Mr. BURTON. Yes. Intermetrics worked with the Volpe National Transportation System to do a special assessment on the AAs.

Mr. HORN. For the FAA?

Mr. BURTON. For the FAA.

Mr. HORN. Where are we on that, by the way? I lost track. I am off the Aviation Subcommittee now.

Mr. BURTON. I think they completely restructured the program and are now going at it through a different approach.

Mr. HORN. But we still haven't delivered anything to the field, have we?

Mr. BURTON. I am actually uncertain about that.

Mr. HORN. I just wondered because last time I was in the tower at Los Angeles International, they were still using Post-It notes on the windows, and since I have flown out of there a few hundred times, I would always like to know the Post-It is stuck in the right place. And they don't make a mistake with it, but it would be nice to have some screens that you could count on.

Let me ask you a few questions, Mr. Zaks. At what point did GTE realize they would be unable to complete the requirements of the original contract of the initial amount of $19 million?

Mr. ZAKS. I would say, Mr. Chairman, that about 18 months into the contract, it was obvious with a lot of the moneys having been spent still in requirements analysis, and requirements themselves having grown substantially, that once we got the design and test, we would be in a position where additional funding would have to be made available.

Mr. HORN. And just for the record, was GTE ever involved in the FAA or the IRS situation?

Mr. ZAKS. No, Mr. Chairman.

Mr. HORN. Where would you rank this particular contract among the many contracts of a similar nature that GTE has handled? What was your biggest one before this?

Mr. ZAKS. Well, we have had several scores of large software developments, and, as with every contractor, you have your successes, and you have those that you would rather not talk about.

The difference between those and this one, I think, is simply the inability to get your arms around either the documentation or the code to sit and use the traditional analysis tools or possibly new analysis tools, to really solidify the requirements, so comparisons are difficult to make.

I don't know much about the details of the FAA problem. I think the IRS problems were very similar, that the code was just unavailable and unavailable to actually analyze.

Mr. HORN. Well, sometimes, as you know, the problem comes with the agency involved where they haven't thought through their systems in a logical way, which is what one translates into software. Now, was any of that a problem, or were you given a fairly logical system that made some sense?

Mr. ZAKS. I think in fairness, there certainly was a system out there that was doing the job. The tools, if they were available, or the documentation to have given a contract the warrant, and I think that HCFA did the best they could in letting in RFP, that they felt was going to permit the development of this system.

And I guess I would like to add, Mr. Chairman, with the requirements analysis process that we have finally, if you will, agreed to, and we did have a couple of false starts, I think we have made significant progress at the time of the stop work. We are certainly well along the way on release 2 requirements. I cannot blame HCFA at all for having taken the action they did, but I don't think it has been wasted. A lot of the moneys we have expended to date is really trying to figure out a process to deal with this lack of hard assets that you can really analyze.

Mr. HORN. Well, I will ask you the same question I asked Dr. Burton. In essence, when did you realize, and if you had to go back, would you do something different than what you did? We all learn

from these things. What do you wish you had done earlier; is there something that stands out that you can help others down the line that will go through this same process?

Mr. ZAKS. I think, you know, hindsight being 20/20.

Mr. HORN. Well, if we don't do it, we won't advance the rest of the operation.

Mr. ZAKS. I think that the major difficulty that both, I think, GTE, HCFA or any IV&V contractor shared was really a need to get out and make decisions on these business rules. We have heard a lot about the business rules. We should have gotten the best we could, get them really in a disciplined fashion to go through them. And one of the things that some of the commercial houses do, they don't count their failures, but they certainly count their successes, is get third parties to arbitrate, people who have no interest, all right, to just arbitrate what the requirements ought to be and arbitrate that process. So it is something that certainly ought to be evaluated, and there are a lot of commercial, you know, industry has been doing that for some time. The statistics on the failures versus the successes obviously is unknown.

Mr. HORN. Does a lot of this get down to on-the-job management and making the decisions that say, hey, we have got to cut it off right here? And we might be a generation behind as a result of that decision, but we might be two generations ahead if we don't do this, because time keeps moving along and we don't play catch-up. Sometimes we try to do that catch-up or make an end run on skipping a beat somewhere that leads us into these morasses, if you will, which is usually funded by money, that go nowhere.

So I am just curious about, in a technical world, what you are dealing with there. We have room management that can pull together a lot of these very bright people that have a lot of wonderful ideas. But, somebody has got to make a decision and say, OK, we are going to go this way now, and I am sorry, but we can't take the last 20 ideas on this subject, we have one we can run with that will solve the problem.

Mr. ZAKS. I think that certainly would have helped us get through a requirements generation phase. The caution there is that the mistakes that would be made, and there would be some, would have to be caught during an extensive test program. But getting 80 percent of the requirements down in a finite period of time would certainly be a bit of damage.

Mr. HORN. Well, we have touched on the next question a little, but I am going to ask it anyhow. Given GTE's experience and working on other information technology projects in a design, planning, implementation role, what is unique about the Medicare claims processing system that affects GTE's ability to meet the contractual requirements? Is there something unique about that system?

Mr. ZAKS. I think, again, the snowballing effect of not having requirements on the size of the design, the size of the test program, the size of the deployment, I mean, is directly related. So unless you can get through a design baseline that can size all the requirements, that is really, in this case, what I would attribute our troubles to.

Mr. HORN. I think you are absolutely right on that, and the fault comes in the administration of the agency not following the guidelines that are both in law, in OMB regulation. I would think in certain planning design phases, one should be going through to think through these implications so that when a contract is awarded, everybody is up to speed on the environment one faces. And I don't know if you heard some of this discussion or you had a chance to look at the GAO report that came out today. That is certainly a point they are trying to make in their recommendations to the Secretary of Health and Human Services as to what she ought to do to direct the Health Care Financing Administration to go back and do a few of these basic things they should have done to start with. I don't know if that is fair or not fair, but that is why we have hearings.

Mr. ZAKS. I guess a comment, Mr. Chairman, is that I am certain if HCFA management recognized the severity of this requirement shortfall, they probably would have taken a different course. I guess it was Mr. Willemssen this morning that talked to a separate requirements contract should have been left prior to a design contract. It is very nice to say that today, and that probably is something they would have chosen, but I think in their defense, they didn't know either just how difficult the requirements would be.

Mr. HORN. Is GTE planning a software capability maturity evaluation performance goal on the MTS software development team as part of your MTS improvement plan, and if so, when will it be done?

Mr. ZAKS. GTE as a matter of course is dedicated and committed to achieving SEI level three maturity by the end of 1998. We have a program that has been in place since 1992. We would have no problem with being audited or having a body come in and validate that program.

Mr. HORN. Since GTE did not know the current level of its software development capability for the MTS team, what is GTE doing to mitigate the risks of being at an undefined level of technical capability?

Mr. ZAKS. Let me say, Mr. Chairman, the part of GTE that is responsible for designing and developing this code is our GTE Data Services Division. They have had a process in place for years. They have been following it probably for two decades. If we who are familiar with SEI go in and analyze what they are and make an assessment, we would probably assess some of their KPAs, key process areas, as very close to three, some in the two plus range. But in their defense, as a group, and being an industrial base primarily, they had a process. They adhere to a process every day. They were just unfamiliar with SEI. They are familiar with it now, and I would not at all be concerned with that group being audited by people coming in.

Mr. HORN. Can you describe for the committee the Health Care Administration management leadership information resources that were available to the GTE team within the MTS project so that communication about evolving requirements was facilitated, what was it like?

Mr. ZAKS. I think that the management team understood, certainly made the decisions. I think that along the way we were all

sort of, I might say, scratching our heads saying that the requirements can't continue to be the size they are.

And so I think that it has taken some time for them to make some significant—take some significant actions. We began to provide metrics in excruciating detail in the September timeframe, the September/October timeframe. If one looks at the metrics associated with release 1, where we have gone beyond requirements, they are pretty much on track. If one looks at release 2, we had the same problem, so I think that is the decisiveness that HCFA management showed.

Mr. HORN. As I understand it, from the General Accounting Office's point of view initially, GTE was meeting with a rather diffuse group of the Health Care Financing Administration staff who really weren't in management positions that would facilitate change and decisionmaking. Is that true?

Mr. ZAKS. I would say that for the first 6 to 8 months or so, it was difficult to get some decisions out of——

Mr. HORN. What kind of a group do you deal with now?

Mr. ZAKS. We deal with a more senior group, a group of people that really feel empowered to make those decisions, and they are doing that. That is why I think——

Mr. HORN. Without objection, there will be an exhibit prepared by staff in the record as to who you met with first and who you are meeting with now, just to give a history of this situation.

Mr. ZAKS. OK.

[The information referred to follows:]

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August 22, 1997

Congressman Christopher Shays
Chairman, Subcommittee on Human Resources
Room B372, Rayburn Building
Washington, DC 20515

Dear Congressman Shays:

Enclosed you will find the material requested during my recent testimony before the Subcommittee on Human Resources and Intergovernmental Relations which took place on May 15, 1997. At that time, GTE was asked to provide a summary list of meetings, meeting participants, and the meeting subject of all meetings conducted with HCFA personnel in regard to MTS Program matters.

The enclosed list represents a subset of those meetings which GTE program personnel considered important in formulating MTS Program policy, decisions, and other related program direction. An entire list of meetings conducted with all HCFA personnel can be assembled, but it is GTE's belief that it would not provide additional visibility into the decision making process which was utilized on the program.

If there are any other questions or material which we can provide to assist the committee, please feel free to contact me at your earliest convenience.

Very truly yours,

Irving Zaks

1994

April 4, - Met with Carol Walton to get her view of MTS.

April 19, - Armen Der Marderosian, Jack Smith, and Karen Roelofs met with Bruce Vladeck to emphasize the importance of MTS to GTE.

April 20, - Met with the staff from the Office of Quality and Evaluation (Ed King, Dave Landis, Sue Lathroum, Frank Delillo, Charles Owens).

April 24, - Met with the staff from the Health Standards and Quality Bureau - Division of Systems Management (Mike Rappaport and Bill Crochunis).

May 23, - GTE, HCFA and Intermetrics met with HCFA Office of Inspector General to hear HCFA concerns on the Medicare Program, direction and needs, and areas for possible improvement in MTS design.

May 25, - GTE, HCFA and Intermetrics met with the GAO to hear GAO views on programmatic considerations and what the GAO felt was needed to improve, correct or change the function and operation of the Medicare Program.

June 30, - Quarterly Management Review to HCFA.

July 8, - Met with HCFA to walk through Deliverable # 6 and discuss changes based on HCFA comments.

June 20, - GTE met with Jared Adair, Dave Landis, Dan Layne and Jim Gordon to discuss the decomposition efforts and GTE approach to requirements.

June 26, - GTE presented the HCFA MTSI group GTE's approach to Deliverable # 8, the MPDB and other analysis activities.

September 13, - Quarterly Review meeting with HCFA.

November 3, - Met with Joe Broseker, Director, Office of Health Care Information Systems

November 9 - 10, - HCFA staff (Carol Walton, Lisa Vriezen, Bob Silva and Elaine Olin) met with members of the GTE MTS Team and GTE management personnel to discuss system design issues that are relevant to MTS.

November 9 - 10, - HCFA and GTE personnel met at GTE's Information Control Center - South (ICC) to see the system previously described in operation. Subsequent to the demonstrations the group met to summarize what had been seen and the implications to MTS.

December 9, - GTE senior management met with HCFA senior management to discuss various topics relating to the MTS program.

1995

February 2-3, - HCFA Review with Carole Walton. Participants included Beth Edwards. Jim Heath, John Messier, Don Hayes and Ed Stephens.

March 9, - Quarterly Management Review with HCFA.

March 16, - Executive Briefing. Beth Edwards and Ed Stephens.

May 1, - Met with C. Walton to discuss HCFA's plan to review Edits along with the Interim Review Package (IRP) process currently in place.

May 20, - Made a presentation to HCFA Senior Management on the status of the Security Project.

June 14, - Quarterly Management Review Meeting.

August 18, - Met with Carol Walton and members of her staff to review an EDI white paper for MTS.

August 31, - Met with Bruce Vladeck and other HCFA Senior Management to present the revised version of the SDA.

October 19 - Security demonstration was held for Steve Pelovitz and HCFA senior management.

October 30 - Met with the GAO regarding MTS status.

1996

January 3, - Presented the SDA briefing on the resized MTS to Steve Pelovitz, Associate Administrator for Operations and Resource Management.

January 4, - Presented the SDA briefing on the resized MTS to Bruce Vladeck, HCFA Administrator.

January 12, - Presented and discussed the Context Diagram and High-Level DFDs and Narratives to HCFA Office Leads.

January 17-18, - Held a Data Workshop with HCFA staff.

January 18, - Presented the SDA briefing on the resized MTS to HHS staff.

January 18, - Delivered proposed changes to HCFA's comments on the SDA.

January 23, - Presented the SDA briefing on the resized MTS to HCFA staff.

January 24, - Presented the SDA briefing on the resized MTS to GAO staff.

January 24, - Presented the SDA briefing on the resized MTS to OMB staff.

July 22, - Executive Management Review (EMR) framework meeting. Jared Adair, Bill Tate, Bruce Burton, Ron Graham, Kathy Carter, Larry Pratt, Kathy Boeschenstein, Joy Garwood

September 16, - GAO visit to BTO.

October 3, - Quarterly Review.

December 19, - Quarterly Review.

1997

January 14-15, - GAO visit to Tampa, FL.

January 24, - Release Managers Meeting hosted by Kathy Boeschenstein and Jared Adair.

February 13, - Telcon between Jared Adair and Irv Zaks

February 18, - Telcon between Jared Adair and Irv Zaks

February 28, - Replan discussions. Irv Zaks, Kathy Boeschenstein, John Magill, Jared Adair, Elaine Olin, Bart Smetana.

March 19, - Replan discussions. Irv Zaks, Kathy Boeschenstein, John Magill, Jared Adair, Elaine Olin, Bart Smetana.

March 20, - Quarterly review and Test Facility meeting

April 4, - Stop Work Order. Irv Zaks, Kathy Boeschenstein, Jared Adair, Steve Pelovitz.

April 24, - Executive Management Review. John Magill and Jared Adair.

May 8, - Executive meeting. Irv Zaks, Steve Pelovitz and Jared Adair.

May 16, - Congressional Testimony.

May 22, - Executive Management Review. John Magill and Jared Adair.

May 29, - Irv Zaks and Jared Adair meeting

June 4, - ITRB. John Magill.

June 5, - Executive Management Review. John Magill and Jared Adair.

June 6, - Executive Management Review. Irv Zaks and Steve Pelovitz

June 18, - Executive Management Review. John Magill, Irv Zaks, Jared Adair, Steve Pelovitz, Elaine Olin, Bart Smetana, Liz Cusic.

June 20, - Executive Management Review. John Magill and Jared Adair.

June 26, - Executive discussions on R1. GTE, Andersen Consulting, HCFA and IV&V. Irv Zaks, Jared Adair, Steve Pelovitz and others

July 16, - Irv Zaks and Jared Adair meeting

July 22, - John Messier, Irv Zaks, Steve Pelovitz and Jared Adair meeting

July 24, - Executive Management Review. John Magill and Jared Adair.

June 25, - Strategy session. John Messier, Irv Zaks, John Magill, Steve Pelovitz, Michelle Snyder, Jared Adair, Dan Kane, Stan Gutkowski.

Mr. HORN. I am curious what difficulties GTE experienced in dealing with and responding to the shifting requirements as the design and development process matured.

Mr. ZAKS. I think that the—it wasn't so much the shifting requirements as much as it was the different approach that we took to it. Initially, we looked at the business rules and we tried to get down to some very specific—almost down to data element levels. It made it very difficult for HCFA management to review, and really, even though at the time they demanded that level, you could not take a step back and say, is this really the business rule. We were down to the ones and zeros. We had some difficulty getting back up to a level where I think we could characterize the business rules, and allow HCFA or management to then make the decision based on their adequacy.

Mr. HORN. Do you feel that basically the requirements were poorly defined when you began this, and they got better as a result of frustration and experience?

Mr. ZAKS. I think the ability to establish the baseline, to establish what we consider the as is, one of the present set of rules that have to be accommodated post-MTS being turned over is where we spent a difficult amount of time. I think people within HCFA had a very good vision as to where they wanted to go in services, but we needed the baseline to actually have a system that we could actually use.

Mr. HORN. Well, that leads into one of my last questions. This is an ultimate question. If Health Care Financing Administration staff had frozen its requirements at some point in the past, could GTE have done a far better job in producing the system?

Mr. ZAKS. Mr. Chairman, there really were no concise set of requirements to freeze. Let me see if I can characterize it a bit differently. For managed care, one of the issues earlier for managed care, it was relatively easy to get through the requirements. The reason for that is twofold. A, we had the code that we could analyze, and we had the people that were available that could very easily sit and as part of the JAD——

Mr. HORN. Do you want to translate?

Mr. ZAKS. Joint analysis development, where you actually sit with your folks and bring that vision to a set of requirements that can be implemented. We did that, and we did that in a reasonable amount of time, and now we can go off and design.

So it is not that they didn't have a set of—it is not that they didn't freeze a set of requirements. I really don't think they had a set of requirements to give us. That is what we have been generating.

Mr. HORN. The last question to you is complexity of the existing systems. What has been the most challenging aspect of the NTA's project for GTE? What do you think has been the most challenging?

Mr. ZAKS. I think it is really a matter of getting the as is, the fee-for-service requirements down into a set of integrated requirements that we can go off and use as a baseline to improve.

Mr. HORN. OK. Let me ask a P.S. Do either one of you want to comment on the testimony you have heard from the other one, just to close out the record? Do you have any comment to Intermetrics and vice versa?

Mr. BURTON. No.

Mr. HORN. We try to give everybody a fair shot.

Mr. ZAKS. No, I don't believe so.

Mr. HORN. OK. We thank you very much for your testimony. It has been most helpful. And maybe when we pull all these experiences together, we will all have learned a lot to save the Government more money in how we go about this in the future.

I want to thank a number of people that helped prepare this hearing. J. Russell George, the staff director for the Government Management, Information, and Technology Subcommittee; Larry Halloran, staff director for the Human Resources Subcommittee. Put your hand up, Larry. You are going to become world famous as a result of this hearing. Mark Uncapher on my left, the counsel who prepared the hearing for us on the Government Management Subcommittee; and Marcia Sayer, professional staff member, Marcia. Thank you all.

Andrea Miller, our clerk down at the end, who keeps things rolling. And our friends over here who have enjoyed this hearing, David McMillen, professional staff member; Mark Stephenson; and Jean Gosa. Where is Jean? There you are down there.

And if we missed a few there, why, you are going to have to work with our staff to fill in the record.

And Vicky Stallsworth, Tracy Petty and Katrina Wright. They are our court reporters.

So thank you very much, and with that, this session is over. Thank you very much.

[Whereupon, at 2:24 p.m., the subcommittees were adjourned.]

[Note.—The GAO Report entitled, "Medicare Transaction System—Success Depends Upon Correcting Critical Managerial and Technical Weaknesses," can be found in subcommittee files.]

[Additional information submitted for the hearing record follows:]

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May 9, 1997

The Honorable Christopher Shays
Subcommittee on Human Resources
Room B-372 Rayburn Building
Washington, D.C. 20515

Fax: 202-225-2548

Dear Congressman Shays:

I am sorry that I could not appear in person to testify before your Subcommittee on "the federal government's approach to biomedical ethics issues in research involving human subjects and the adequacy of informed consent". This week is the last week of classes at Yale Law School and, thus, my students' needs require my presence at the school.

I shall limit my comments about the adequacy of the federal regulations for the protection of human subjects in research to two issues and attach two brief publications in support of my contentions. Since in your letter you also mentioned the Nuremberg Code, I am sending you under separate cover a copy of a speech I delivered last October at Nuremberg on the 50th Anniversary of the Nazi Doctors' Trial which Dean Anthony Kronman distributed to the 10,000 alumni/ae of the Yale Law School.

1. Adequacy of Informed Consent: I recently served on the Presidential Advisory Committee on the Human Radiation Experiments conducted during the Cold War. As part of our task we reviewed research proposals and informed consent forms from a random sample of research approved and funded in fiscal years 1990 through 1993 by DHHS, DOD, DOE, VA and NASA. The Advisory Committee found in its review "that there are serious deficiencies in some aspects of the current system for the protection of human subject by [not providing] Institutional Review Boards [IRBs] with enough information about topics that are central to the

ethics of research; [and equally important the Committee found] that some consent forms currently in use are flawed in morally significant respects, not merely because they are difficult to read but because they are uninformative or even misleading...." (see Final Report of Advisory Committee on Human Radiation Experiments pp. 694 - 723).

I independtly reviewed about 100 if the research proposals submitted to us (significantly more than each individual member of the Committee did). My review, that focused solely on the informed consent process came to more troublesome conclusions: "50% [of the submitted projects] raise serious ethical concerns [about the adequacy of informed consent] and an additional 24% raise ethical concerns that cannot be taken lightly." (See Appendix A - "Statement by Committee Member, Jay Katz" - for a more extensive discussion of my findings).

2. The Function of IRBs and the Need for a National Human Investigation Board: In response to the 1994 proposal by the Office of Science and Technology Policy to establish another Advisory Commission on Human Experimentation, I wrote a brief article in the Hastings Center Report (See Appendix B) in which I once again set forth my arguments that IRBs, under the current system cannot fulfill the tasks they are supposedly to serve: "IRBs are forced to make decisions that are compromised by the limited time and resources available to them; by their lack of expertise, which prevents them from considering in any depth the complex legal, ethical, and societal problems that human experimentation poses; and by the pressures of their institutional colleagues to approve their protocols as quickly and unquestioningly as possible."

Instead, I proposed, as we already had done in 1973 in the Final Report on the Tuskegee Syphilis Study, that Congress "establish a permanent body [we called it the National Human Investigations Board] with the authority to *regulate* at least all Federally supported research involving human subjects." The Board, we suggested, should be independent of the Department of Health, Education and Welfare (now HHS), for we did not believe that "the agency which both conducts [research] and supports much of the research that is carried on elsewhere is in a position to carry out disinterestedly the functions we [have] in mind." Most importantly we recommended that the Board must not only *promulgate* research policies but also *administer* and *review* the human experimentation process. Constant interpretation and review by a Body that is not advisory but whose decisions count by virtue of the authority invested in them, can protect subjects of research from unconsented intrusions into their bodies and minds which our Constitution and Bill of Rights seek to safeguard for citizens, including patient-subjects of research.

In formulating research policies, an important task of such a Board would be to define exceptions to the informed consent requirements in research with children and with temporarily or permanently incompetent subjects. For example, when might it be permissible, as is now being done, for IRBs to "defer consent' (or more correctly, to allow physician-investigators to proceed without consent) with patient-subjects suffering from acute head trauma? Conscripting citizen-patients to anything they have not consented to is deeply offensive to democratic values and, whenever necessary, requires public approbation.

In your press release of May 2, 1997, you correctly identified many of the problems that plague the current system of human research subject protection. Let me add, in conclusion, a few comments on your statement to the press: (1) It is true that "IRBs have been described as 'the cornerstone' for ensuring the protection and ethical treatment of human subjects." While IRBs -- some performing their assignments better than others have tried to shoulder this task, -- I have indicated above, and more extensively in other articles (see for example, "Human Rights and Human Experimentation," 38 St. Louis University Law Journal 7-54, 1993) that it is illusory to consider them "cornerstones". (2) Moreover, you too noted that "[t]here is no national body to monitor bioethics issues". The appointment of such a body is urgently needed. Not only is bioethical research conducted at an ever increasing rate, but new ethical issues constantly arise that require careful ethical deliberation; for example, genetic research, research with embryos, AIDS research in the USA and foreign countries supported by HHS, research on patients suffering from acute head trauma who cannot give their consent, research with mentally incompetent patients for whom, at present, no adequate federal safeguards exist.

(3) Perhaps OPRR could assume the function of such a National Body. If that idea, to which I want to give more thought, has merit, it would require that its staff be vastly expanded, made independent of HHS, and superintended by a Committee of representatives from many disciplines as well as the public who probably should be appointed by Congress.

Once again, I want to express my regrets for not having been able to attend your important Hearing this week when I could have responded to the many questions you might have wanted to ask me. If I can be of further assistance to you, do not hesitate to call on me. I have thought deeply during the last 30 years about how to resolve the inevitable tensions inherent in the conduct of research: protection of the inviolability of subjects of research, on the one hand, and the need to advance medical knowledge on the other.

Cordially yours,

Jay Katz

JK/pls
Enclosures

APPENDIX A

STATEMENT BY COMMITTEE MEMBER JAY KATZ

We were assigned two tasks: to examine the past and to examine the present. Telling the full story of government sponsored Cold War human radiation experiments serves many important purposes--remembrance, warning, healing. Ultimately, however, the value of knowing the past resides in the lessons it can teach us for the present and future. Thus, the central question is this: Do current regulations of human experimentation adequately protect patient-subjects? Here I have the most serious reservations about our Report.

In summary, my conclusions are these: (1) In the quest to advance medical science, too many citizen-patients continue to serve, as they did during the Cold War period, as means for the sake of others. (2) The length to which physician-investigators must go to seek "informed consent" remains sufficiently ambiguous so that patient-subjects' understanding of the consequences of their participation in research is all too often compromised. (3) The resolution of the tensions inherent in the conduct of research--*i.e.*, respect for citizen-patients' rights to, and interest in, self-determination on the one hand and the imperative to advance medical science, on the other--confronts government officials with policy choices that they were unwilling to address in any depth during the Cold War or for that matter in today's world. (4) Our Recommendations only touch on these problems and at times make too much of the safeguards that have been introduced since 1974. The present regulatory process is flawed. It invites in subtle, but real, ways repetitions of the dignitary insults which unconsenting citizen-patients suffered during the Cold War.

Medical research is a vital part of American life. The Federal government allocates billions of dollars to human research, and the pharmaceutical industry spends many more billions to develop new drugs and medical devices. And research is by and large conducted with patients. Since all of us at one time or another will be patients, we are readily available subjects for research. Thus, the protection of the rights and interests of citizen-research subjects in a democratic society is a major societal concern.

Let me introduce my Reservations by offering some preliminary remarks about the current regulatory scheme and the history of consent. The contemporary regulatory scheme provides insufficient guidance for addressing one basic question: When, if ever, should conflicts between advancing medical knowledge for our benefit and protecting the inviolability of citizen-subjects of research be resolved in favor of the former? Inviolability, unless patient-subjects agree to invasions of mind and body, requires punctilious attention to disclosure and consent and, in turn, imposes considerable burdens on physician-investigators--be it taking the necessary time to converse with patient-subjects or,

Statement

if necessary, making discomforting disclosures. Moreover, taking informed consent seriously may slow the rate of medical progress with painful consequences to investigators' work and to society. These dilemmas must be resolved forthrightly, instead of allowing them to be "resolved" by discretionary subterfuge.

Neither the drafters of the 1974 Federal Regulations nor the members of the research community were willing to respond to the reality that taking informed consent seriously in this new age of informed consent confronted them with problems that required sustained and thoughtful exploration. Implementation would also turn out to be a most formidable task because of physicians' low regard for patient consent throughout medical history. The Committee's analysis of the informed consent requirements in existence during the Cold War and earlier in the 20th century acknowledges, but not sufficiently so, that the millennia-long history of medical custom casts a dark shadow over what transpired during the Cold War.

Patient consent, until most recently, has not been enshrined in the ethos of Hippocratic medicine. As I once put it, the idea of patient autonomy is not to be found in the lexicon of medicine. It is important to be aware of this history; for it explains why our Findings on contemporary research practices, which time constraints prevented us from probing in sufficient depth, revealed deficiencies in the informed consent process, both at the levels of physician-investigator interactions with their patient-subjects and of IRB review. This is not surprising; for not only does it take time to change historical practices, it also requires more thoughtful rules and procedures than currently exist.

My reading of the Cold War record suggests that governmental officials in concert with their medical advisers at best paid lip service to consent. Whenever they considered it, they worried mostly about legal liability and embarrassment. They were not worried or embarrassed about their willingness to conscript unconsenting patient-subjects to serve as means in plutonium and whole body radiation experiments. All this is a frightening example of how thoughtlessly human beings, including physicians, can treat human beings for "noble" purposes. Most references to consent (with rare exceptions) that we uncovered in governmental documents or in exchanges between officials and their medical consultants were meaningless words, which conveyed no appreciation of the nature and quality of disclosure that must be provided if patient-subjects were truly to be given a choice to accept or decline participation in research. Form, not substance, punctuated most of the policies on consent during the Cold War period. The drafters of the Federal Regulations would eventually build their rules on this shaky historical foundation, disregarding in the process that the imprecision of their policies invited physician-investigators not to alter decisively customary Hippocratic practices.

The long established tradition of obtaining consent from healthy subjects

> is firmly put into practice can one address the claims of science and society to benefit from science. Only then can one avoid the dangers that accompany a balancing of one principle against the other that assigns equal weight to both; for only if one gives primacy to consent can one exercise the requisite caution in situations where one may wish to make an exception to this principle for *clear and sufficient* reasons.

I mention this here because the final and most far-reaching recommendation for change that I shall soon propose is based on two premises: (1) that any exception to the principle of individual autonomy, since it tampers with fundamental democratic values, must be rigorously justified by clear and sufficient reasons; and (2) that such exception cannot be made by investigators or IRBs but only by an authoritative and highly visible body.

I now turn to our Research Proposal Review Project. The Committee's review of contemporary research reveals that of the greater-than-minimal-risk studies (which are the ones that raise complex informed consent issues) 23% were ethically unacceptable and 23% raise ethical concerns. My own independent review tells a grimmer story: 50% raise serious ethical concerns and an additional 24% raise ethical concerns that cannot be taken lightly. Since I focused exclusively on the informed consent process, the differences in our Findings can perhaps in part be explained on that basis. My data, like the Committee's, were the protocols submitted to IRBs and the informed consent forms signed by patient-subjects. I appreciate that the evidence available to us does not reflect what patient-subjects might have been told during oral communications. But if the protocols and patient-subject consent forms are flawed in significant ways, it is likely that the oral interactions are similarly flawed. Moreover, since IRBs are charged to pay particular attention to the informed consent process, I contend that IRBs should not have approved the problematic consent forms in the form they were submitted. The forms often seem to "sell" research rather than to convey a sense of caution that invites reflective thought.

I had expected to discover problems, but I was stunned by their extent. Consider what we observed in Chapter 15 and what is described there in greater detail: The obfuscation of treatment and research, illustrated most strikingly in Phase I studies, but by no means limited to them; the lack of disclosure in randomized clinical trials about the different consequences to patient-subjects' well being if assigned to one research arm or the other; the administration of highly toxic agents, in the "scientific" belief that only the knowledge gained from "total therapy" will *eventually* lead to cures, but without disclosure of the impact of such radical interventions on quality of life or longevity. I do not wish to minimize the impact of making total disclosure on patient-subjects' and physician-

investigators' hopes and fears. Yet, nagging questions remain: What are "clear and sufficient reasons" which permit tampering with disclosure and consent; and, if permissible, who decides?

Our Recommendations do not go far enough in remedying the flawed nature of our current regulations which appear to rely so heavily on informed consent, but which in practice I contend, bypass true informed consent. Here I can only make a few comments about the changes required if we wish to protect adequately the rights and interests of subjects of research:

(1) *Informed consent* is central to such protections. The drafters of the Federal regulations have acknowledged that fact. They have failed, however, to take responsibility for making these requirements meaningful ones. Thus, patient-subjects now all too often give a spurious consent; a "consent" that can readily mislead physician-investigators into believing that they have received the authority to proceed when in fact they have not.

(a) The Federal regulations imply that the principle of respect for patient-subjects' autonomy is central to the regulatory scheme. Leaving it at that is not enough; for the principle requires commentary so that physician-investigators will have a more thoroughgoing appreciation of the moral issues at stake whenever they ask human beings to serve as means for the ends of others. Only then will they learn, for example, that to take informed consent seriously requires them to spend considerable time with prospective patient-subjects and to engage them in searching conversations. In these conversations they must disclose (a) that their subjects are not patients or, to the extent they are patients, that their therapeutic interests will be subordinated in specified ways to scientific interests; (b) that it is problematic (and in what ways) whether their welfare will be better served by placing their medical fate in the hands of a practitioner rather than a physician-investigator; (c) that in opting for the care of a physician they may be better or worse off and for such and such reasons; (d) that research is governed by a research protocol and a research question and therefore patient-subjects' interests and needs have to yield (and to what extent) to the claims of science; etc.

Such disclosure obligations are formidable ones. They need to be fulfilled in a manner that will give patient-subjects a clear appreciation of the difference between research and therapy, and in the spirit that disabuses them of the belief, so widely held--as our Subject Interview Study demonstrates-- that everything the investigator proposes serves their best therapeutic interests.

The Cold War experiments teach us that misplaced trust can deceive; that trust must be *earned* by prior disclosures of what research participation entails. I agree, as our Recommendation 9 proposes, that scientists should be educated "to ensure the centrality of ethics in [their] conduct." To accomplish that educational task, however, requires policies that more clearly delineate the ambit of discretion which investigators can exercise in the conduct of research.

(b) Current criteria for informed consent encourage, perhaps even

mandate, overwhelming patient-subjects with information on every conceivable risk and benefit as well as on the scientific purpose of the study. Adherence to these mandates has led, and justifiably so, to concerns about the incomprehensibility of the informed consent forms that patient-subjects must sign. Much thought, and then guidance, has to be given to IRBs and investigators as to the essential information they most provide; *e.g.*, alternatives, uncertainties, essential risks, realistic benefits as well as the impact of participation--known and conjectured--on the quality of future (or remaining) lives. Many of the informed consent forms I have examined fail to emphasize the risks germane to the research protocol; instead they go into numbing detail on risks that can be summarized. To put it bluntly: Informed consent criteria in today's world, at least in the ways they are communicated to patient-subjects, often serve purposes of obscuring rather than clarifying what participation in research entails.

(2) Though *IRBs* serve important functions, they do not have the capacity, if only by virtue of composition and lack of time, either to modify consent standards (including the ones I have just proposed) or, more generally, to make any other decisions that could affect the fundamental constitutional rights and personal interests of subjects of research. IRBs should not have the authority to decide how to balance competing principles in situations where the competence of subjects' consent is in question, or where consent cannot be obtained because patient-subjects suffer from a life-threatening condition, or where other complex issues need to be resolved, as illustrated in our Chapter on the total body radiation experiments. Such fateful decisions are beyond their competence.

Moreover, IRBs work in a climate of low visibility, another species of secrecy about which we expressed so much concern in Chapter 13. These and other complex ethical problems should only be resolved by an *accountable* and highly *visible* national Body. That Body then can provide IRBs with guidelines that will better inform their deliberations. I would like to note here, but only in passing, that the Body I envision will lighten IRBs' tasks; for example, by fashioning policies for cursory review of the many minimal/no risk studies, or by being available for advisory opinions whenever IRBs are confronted with new ethical problems. (IRBs now spend an inordinate amount of time on such problems which they should not resolve in the first place.) The national Body should not review individual research projects except when investigators and IRBs disagree. Finally, a national Body is needed for another reason as well: The considerable pressure for approval of protocols to which IRBs are subjected by the scientists at their institutions.

(3) Already in 1973, when I served on HEW's Tuskeegee Syphilis Study Ad Hoc Advisory Panel, we proposed in our Final Report that Congress establish a permanent body--we called it the *National Human Investigation Board*--with the authority to regulate at least all Federally supported research involving human subjects. We recommended that this Board should not only *promulgate* research

policies but also *administer* and *review* the human experimentation process. Constant interpretation and review by a Body whose decisions count by virtue of the authority invested in them can protect both the claims of science and society's commitment to the inviolability of subjects of research.

A most important task which such a Board would face in formulating research policies is to delineate exceptions to the informed consent requirement when competing principles require it. For example, when might it be permissible for IRBs to "defer consent" (or more correctly, to allow physician-investigators to proceed without consent) with patient-subjects suffering from acute head trauma? Conscripting citizen-patients to anything they have not consented to is deeply offensive to democratic values and, if necessary, requires public approval. Greater public participation in the formulation of research policies is vital, and the Board must therefore establish procedures for the publication of all its major policy and advisory decisions, particularly those where compromises seem warranted between the advancement of science and the protection of subjects of research. Publication of such decisions would not only permit their intensive study both *inside* and *outside* the medical profession but would also be an important step toward the case-by-case development of policies governing human experimentation. If we are truly concerned about the baneful effects of secrecy on public trust, what I propose here could restore trust.

There is, of course, much more to consider, and I have written about it elsewhere. I hope, however, that I have said enough to suggest that the problems inherent in research with human subjects--advancing science and protecting subjects of research--are complex. Society can no longer afford to leave the balancing of individual rights against scientific progress to the low-visibility decision-making of IRBs with regulations that are porous and invite abuse. The important work that our Committee has done in its evaluation of the radiation experiments conducted by governmental agencies and the medical profession during the Cold War once again confronts us with the human and societal costs of too relentless a pursuit of knowledge. If this is a price worth paying, society should be forced to make these difficult moral choices in bright sunlight and through a regulatory process that constantly strives to articulate, confront, and delimit those costs.

We have judged the past and judgments of the past become most relevant when they teach us lessons for the present and future. Yet, we did not judge the present with sufficient care. If the problem was time, I wanted to take the time to offer my judgments. I also took the time and "took [the road] less traveled by" because much is at stake in the quest for advancing medical science that speaks not only to progress in the conquest of disease but to other moral values as well.

APPENDIX B

Do We Need Another Advisory Commission on Human Experimentation?

by Jay Katz

Instead of another federal advisory panel to identify ethical principles governing human subjects research, it is time we had a national board with authority to regulate and review such research.

A few months ago the Office of Science and Technology Policy (OSTP) published in the *Federal Register* its proposal for the establishment of another "Bioethics Advisory Commission within the Executive Branch . . . to consider issues of bioethics arising from research on human biology and behavior, and the application of that research." Central to OSTP's proposal is an "inquiry" into the adequacy of the current "protection of the rights and welfare of research subjects, [i.e.] informed consent, adequacy and implementation of Federal human subject research guidelines, and the concept of 'minimal risk.'"

We do not need another inquiry, another advisory commission on human experimentation. We need a national commission that has the authority, with the advice of Congress, to regulate all research involving human subjects. We have had enough advisory bodies: the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research (1974-78) and the President's Commission for the Study of Ethical Problems in Medicine and Biomedical and Behavioral Research (1979-83). Both made remarkable contributions and left us a rich legacy of ethical, legal, and policy analysis as well as recommendations for the conduct of research. To be sure, as OSTP noted, members of the contemplated commission could "expand on their work," but I doubt whether they would shed significant new light on "the broad overarching principles to govern the ethical conduct of research." (OSTP assigned two other tasks to the advisory commission, but was correctly concerned that one of them was itself so broad in scope that it might "limit [the commission's] effectiveness." In what follows, I make no judgment about the need for advisory commissions in areas unrelated to human experimentation.)

The current impetus for establishing another advisory commission is fueled, as its chief supporter Senator Mark Hatfield suggested in a letter to President Clinton, by the "disclosures of radiation testing on humans during the Cold War [that] have raised profound ethical questions for Federal policy makers." Twenty-two years ago, the revelations regarding the Tuskegee syphilis study, conducted by Public Health Service physicians from 1932 to 1972, led to a similar call for more stringent oversight of the human experimentation process which in 1974 culminated in the promulgation of the federal regulations for the protection of human research subjects. The regulations, while an improvement over what we had before, are inadequate. Indeed, in its final report, the Tuskegee Syphilis Study Ad Hoc Advisory Panel of the Department of Health, Education and Welfare recommended an entirely different approach to the regulation of human experimentation. I chaired the subcommittee that addressed this charge. Now twenty years later, our recommendations deserve reconsideration. Before describing them, I want to proffer two observations:

(1) The federal regulations, promulgated in 1974 at the prodding of Senator Edward Kennedy and others, essentially codified criteria for informed consent in the conduct of research and, with limited and vague additional instructions, left it to local institutional review boards (IRBs) to review—"approve, require modification in, or disapprove"—research proposals submitted by their local institutions. Thus, IRBs are forced to make decisions that are compromised by the limited time and resources available to them; by their lack of expertise, which prevents them from considering in any depth the complex legal, ethical, and societal problems that human experimentation poses; and by the pressures of their institutional colleagues to approve their protocols as quickly and unquestioningly as possible. In short, IRBs are left at sea, given a mandate that they could not responsibly carry out without recourse to an overarching body that would structure and guide their work.

(2) Already in 1973, it was clear that more was needed than what the federal regulations provided. During this century, and particularly since World War II, biomedical research has in-

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creased in magnitude unprecedented in the millennia of medical history. Medical practice has become radically transformed, often obliterating the vital distinction between therapy and scientific research. This problem is compounded by physician-investigators' proclivities to view subjects as if they were patients, treating the latter with the discretion and authority doctors have customarily enjoyed when making decisions *for* rather than *with* patients. Readily overlooked in the process are physicians' obligations—inevitably compromised by the dictates of a research protocol designed to advance knowledge for the sake of future patients and society—to attend to the well-being of individual patients. Thus, the increasing use of human beings as means for the ends of others can undermine basic democratic values of citizens' rights to autonomy and self-determination. Moreover, physician-investigators in their understandable scientific pursuit of alleviating the suffering of mankind, have been reluctant to think deeply about the philosopher Hans Jonas's observations that "[medical] progress is an optional goal, not an uncompromising commitment," and that "too ruthless a pursuit of scientific progress" could threaten "the erosion of moral values . . . that would make its most dazzling triumphs not worth having."[1]

In the final report of the Tuskegee Syphilis Study Ad Hoc Advisory Panel we went beyond what OSTP recommends: "to identify broad, overarching principles to govern the conduct of research." To be sure, we need principles, but overarching principles do not serve us well unless we have mechanisms in place for the *interpretation* and *application* of principles whenever they come face to face with science's and investigators' competing interests, motivations, and objectives; for *review* of the decisions made by those charged with implementing the principles; and for the constant *refinement* of the criteria and procedures that should govern the conduct of research. Principles alone may assuage our conscience but they also allow us to go on sinning.

In our final report we proposed that Congress "establish a permanent body [we called it the National Human Investigation Board] with the authority to *regulate* at least all Federally supported research involving human subjects." The board, we suggested, should be independent of the Department of Health, Education and Welfare, for we did not believe that "the agency which both conducts [research] and supports much of the research that is carried on elsewhere is in a position to carry out disinterestedly the functions we [had] in mind." Most importantly we recommended that the board must not only *promulgate* research policies but also *administer* and *review* the human experimentation process. Constant interpretation and review by a body that is not advisory but whose decisions count by virtue of the authority invested in them, can protect both the claims of science and society's commitment to the inviolability of subjects of research.

In formulating research policies, a most important task the board would face is to define exceptions to the informed consent requirement in research with children and with temporarily or permanently incompetent subjects. For example, when might it be permissible, as is now being done, for IRBs to "defer consent" (or more correctly, to allow physician-investigators to proceed without consent) with patient-subjects suffering from acute head trauma? Conscripting citizen-patients to anything they have not consented to is deeply offensive to democratic values and whenever necessary requires public approbation. To secure greater public participation in formulating research policies, we suggested that the board establish procedures for the publication of all its major policy and advisory decisions, particularly those where compromises seem warranted between the advancement of science and the protection of subjects of research. Publication of such decisions, we believed, would not only permit their intensive study both *inside* and *outside* the medical profession but would also be an important step toward the case-by-case development of policies governing human experimentation.

I can only sketch some of the other important tasks that a national human investigation board must undertake. It must establish guidelines (1) for the selection of subjects, such as the extent to which fairness dictates that patient-subjects represent a cross-section of the population, or the circumstances in which vulnerable populations (prisoners or terminally ill patients) can participate in research; (2) for modification of informed consent requirements, particularly with children and with comatose and other mentally disabled persons who will not benefit from the research; (3) for the compensation of subjects harmed as a consequence of their participation in research; (4) for categories of "innovative treatments" that should not be exempt from IRB review; (5) for the resolution of any conflicts between investigators and IRBs about proposed research.

I want to emphasize that it is not only important that the national board promulgate guidelines but also that it be available to IRBs for advice and consultation whenever the guidelines require interpretation. But only on rare occasions should the board review individual research protocols. This could happen when serious allegations have been made by interested parties about violations of existing policies. When the research they propose raises new ethical problems, however, IRBs should be encouraged to ask for a ruling whether and how to conduct it. For example, in the acute head trauma study referred to above, an IRB would be expected to seek review of its intentions to allow investigators to defer obtaining consent from relatives for a few days.

Moreover, in its administrative role the national board, once policies have been formulated, must develop criteria for protocols that do not require IRB review. This would reduce the impossible tasks IRBs now face in reviewing all research proposals. Furthermore, workable standards need to be developed for informed consent. The current informed consent forms are largely incomprehensible and overwhelm subjects with information that distracts from what they need to know to arrive at a meaningful decision. Again, IRBs are now constrained, and have nowhere to turn to modify these forms, since in

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theory, doing so might violate federal mandates.

The board would also have to consider whether current research methodologies are in need of modification. For example, when evaluating drugs, pharmaceutical companies often insist that placebo controls and double blind randomized clinical studies be employed. Both, to be sure, are considered "the gold standard of research methodology." But sometimes other methodologies must be considered to avoid exposing patient-subjects to undue harm. In a recent study, half of seriously depressed patients were assigned to the placebo arm of an investigation, even though the efficacy of available antidepressant medications had already been established. Thus, these questions: When must research designs depart from the "gold standard" so that subjects of research will be adequately protected? When are placebo controls necessary and when must other methodologies be employed to obtain scientifically valid results?

There is more but I hope that I have said enough to suggest that the problems inherent in research with human subjects—advancing science and protecting subjects of research—are immense. Society can no longer afford to leave the balancing of individual rights against scientific progress to the low-visibility decision-making of IRBs with regulations that are porous and invite abuse. A new ethics advisory commission will surely once again affirm a commitment to the rights of individuals. But once that has been accomplished, it will not be there to administer and review the human experimentation process and provide guidance for the complex problems that human research constantly poses. The recent revelations about the radiation experiments conducted by governmental agencies and the medical profession once again confront us with the human and societal costs of too relentless a pursuit of knowledge at the expense of other moral values. If this is a price worth paying, society should be forced to make these difficult moral choices in bright sunlight and through a regulatory process that constantly strives to articulate, confront, and delimit the costs.

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1. Hans Jonas, "Philosophical Reflections on Experimenting with Human Subjects," *Daedalus* 98 (1969): 219-47, at 245.

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